Outbreak Investigation, Acute Gastroenteritis
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Outbreak Investigation
Acute Gastroenteritis

Overview

The purpose of this section is to provide general guidelines, including a decision tree, for the process of investigating a suspected communicable disease outbreak. Outbreak investigations can be overwhelming for a single person, and should be a collaborative effort whenever possible. Notify the District Communicable Disease (CD) Coordinator immediately when a report of a suspected outbreak is received.

While every outbreak is unique, the investigative process generally follows a series of steps that are defined in the following decision tree. Although no outbreak will follow the steps in exact order, the decision tree provides an excellent guideline for the things that need to be considered in any investigation.

It is important to stress that several of these steps may occur simultaneously, that their order of occurrence will likely vary, and that several of the steps may occur more than once. However, all of these things are necessary to the successful resolution of an outbreak.

Preparation for the Outbreak Before it Occurs

- Establish a multidisciplinary investigative team (i.e., nursing, communicable disease, environmental, support staff, laboratory, public information, and computer information specialists) and assign responsibilities.
- Train staff (attends Principles of Epidemiology and other disease specific courses on investigative procedures).
- Assemble materials (laboratory kits, forms, reference materials, personnel protective equipment (i.e., gloves, masks).
- Maintain a current phone directory, including e-mail and Internet addresses, home addresses and phone numbers of team participants, and key contact personnel outside the Local Public Health Agency.
- Maintain a sentinel surveillance system to compare the number of new disease cases (incidence) with the historical incidence of similar cases for a similar time period for the early detection of increased disease incidence.

Investigation Decision Tree

Key Points:

- Communicate early, often, and accurately.
- Establish regular communication among local, state, and federal agencies.
- Understand roles / responsibilities of agencies conducting investigations.
- Develop and use standard procedures / tools to allow for interagency consistency.
- Identify agency / department leaders and points of contact prior to an outbreak.
- Develop and maintain contact lists.

HOW TO HANDLE A REPORT OF AN OUTBREAK

A report of a suspected outbreak may be received in a variety of ways (e.g., active/passive surveillance systems, concerned citizens, healthcare provider, media, law enforcement, etc.) The purpose of these guidelines is to recommend procedures for investigating confirmed or suspected cases associated with an outbreak. All outbreaks or "suspected" outbreaks must be reported as soon as possible (by phone or e-mail) to the District CD Coordinator. Follow-up initial outbreak report by submitting a CD-51, Missouri Outbreak Surveillance Report (Section 30.1). **If a bioterrorism event is suspected, notify your district CD Coordinator and appropriate law enforcement officials immediately.**

1. **Obtain initial report from notifier; information to be obtained:**
   - Identify person making report; obtain name and phone number if possible.
   - Point of contact for the situation – name and phone number if different than person making report.
   - Identify person(s) or groups ill, number of ill (how many potentially exposed).
   - Record date and hour of onset, duration of illness, for the first few known cases.
   - Date and time of any event thought to be related to the outbreak cause (names of person(s) or common gatherings within appropriate incubation period for illness, or initially the previous 72 hours).
   - Location of illness in community, address.
   - Record signs and symptoms of illness.
   - Suspected mode of transmission (e.g., ingestion, inhalation, or direct contact exposure).
   - Diagnosis of illness (laboratory findings or physician diagnosis).
   - Reporter's hypothesis as to cause of illness.

2. **Are there other associated cases? Determine extent of illness:**
   - Does this case have the same diagnosis, laboratory findings, or syndrome as any previously or currently reported case(s)?
   - Implement survey in affected area and contact medical providers (i.e., primary care physicians, hospital emergency rooms, High Alert surveillance sites) in area to identify if associated cases are present.
     - **Yes** ®
       - Expand investigation to identify additional cases, persons at risk, and associations between the cases to identify exposure(s).
       - Develop interview questions and design an outbreak questionnaire based on information from initial surveys (person, place and time variables). If the exposure times are known, use the incubation periods listed in Section 30.7 "Table of Common Etiological Agents Classified by Symptoms and Incubation Periods" to assist in developing a list of possible agents. If the agent is known, use the incubation periods to identify possible times of exposure.
     - **No** ®

- Epidemiological investigations of single cases of illness are generally not fruitful. If no associated cases have been identified, and the agent is known, follow the procedures in the appropriate disease section of this manual. Report case utilizing CD-1 Report form, and form CD-2C, "Record of Investigation of Enteric Illness", for all enteric cases. If the agent is unknown, maintain a record of possible exposures in the event additional cases are reported.

3. Is agent transmissible from person-to-person?

- **Yes** ®
  - Investigate place of exposure (if known) to determine/identify others who may have been exposed when the identified person(s) was exposed.
  - Determine when the identified case(s) was infectious.
  - Identify contacts for possible secondary transmission.
    - If person (case) is currently infectious, recommend practices to prevent further transmission of the illness.
    - If person is no longer infectious, then focus on previous contacts who may be incubating, or who may be onsetting with the disease.
- **No** ®
  - Target place of exposure to find others who may have been exposed when the identified case(s) was exposed.
- **Unknown** ®
  - Proceed as if the agent were transmissible.

4. Conduct investigation.

- Notify team members from appropriate disciplines. Team members may also include personnel from several agencies and levels of government (DHSS, CDC, FDA, USDA, DNR, or the private sector).
- Select a team leader to coordinate the outbreak and make job assignments.
  - If outbreak encompasses multijurisdictional areas / agencies, consult with District CD Coordinator to assist with determining appropriate lead agency.
- For all **ill** cases identified, obtain appropriate information: >>
  - Complete appropriate investigation form / outbreak questionnaire on all persons associated with event. >>
    - Submit completed CD-1 Case Report on all confirmed / probable cases (see case definition for specific diseases).
  - If agent is transmissible person-to-person, complete appropriate investigation form / outbreak questionnaire on contacts of cases. >>

- Collect clinical specimens. >>
    - Determine what clinical specimens have been collected by health care providers and obtain results. As soon as an outbreak is apparent, have the laboratory save the specimens for further specialized testing by the State Public Health Laboratory (SPHL). >>
    - Consult with the District Communicable Disease Coordinator and SPHL for what additional specimens may be necessary.
    - Refer to the protocol in subsection 30.4, "Criteria for Submitting Lab Specimens", when the causative agent in a gastrointestinal outbreak has not been identified.
- Conduct environmental assessment and collect specimens. >>
    - When a suspect establishment, event, and/or means of transmission (i.e., food) is identified, the Environmental Public Health Specialist should inspect the site and collect the appropriate specimens. >>
        - Refer to subsection 30.5, "Guidelines for Submission of Food Samples for Bacteriological Analysis in Outbreaks".
    - Coordinate analysis of both clinical and environmental specimens with the SPHL.
- Select comparison group (non-ill persons) and obtain appropriate information for a risk assessment.
    - Statistical analysis of outbreak data cannot be performed without a non-ill group or persons at risk who did not become ill.

5. Formulate a case definition.

- Combine clinical characteristics, laboratory test(s), and epidemiological information into criteria for the categorization of cases. See Section 30.11, "Confirmatory Methods of Etiologic Agents including Incubation Periods and Clinical Symptoms".
- Prepare a line list of relevant case information that has been gathered (See Section 30.2 Sample Line List; categories on line list may be expanded as necessary).
- Categorize the cases according to the case definition. >>
    - **ILL** ®
        - Confirmed case – implement appropriate control measures.
        - Probable / Suspect case – implement appropriate control measures.
        - Presumptive case – implement appropriate control measures.
        - Ill, but does not meet case definition – monitor to see whether individual develops signs and symptoms characteristic of the agent; if so, refer to health care provider for testing and possible treatment.
    - **WELL** ®
        - Well, had appropriate exposure – implement appropriate control measures (used for case study).
        - Well, did not have appropriate exposure – educate individuals on agent and alert them to visit their health care provider if they become ill.

    Exposed = exposed to event. Or, if transmissible person-to-person, **Exposed** = exposed to case(s). Case control studies of common-source outbreaks generally exclude secondary cases from analysis.

6. **Analyze the cases and characterize by time, place, and person.**
   - Analyze the data to identify differences in exposure frequencies between the ill and well groups, to confirm or refute the hypothesis. As data from the interviews is analyzed, it may be necessary to modify the direction of the investigation or to formulate a new hypothesis.
   - Select the categories to be analyzed for risk factors and/or associations using EpiInfo or other suitable statistical computer software such as SAS.
   - Prepare a frequency distribution of cases by location and by personal characteristics, obtain denominator data to calculate attack rates and distributions for each – identify associations / risk factors.
   - Create epi curve (histogram) that reflects onset time and incubation period for the organism.
   - Statistical expertise is available from the District Communicable Disease Coordinator.

7. **Formulate hypotheses of the agent.**
   - Interpret available data to determine:
     1. Identity of most likely agent.
     2. Likely source of agent.
     3. Likely mode or means by which agent was transmitted.
   - The tentative hypothesis is constructed from time, place, and person associations and is the basis for the initial outbreak definition and case definition. The hypothesis should be written as soon as enough information is available. It is very important not to be too restrictive in your focus; thereby excluding potentially important cases or events by focusing too closely on one hypothesis.

8. **Select and implement control measures specific for the identified organism.**
   - Implement the control measures that are indicated by the analysis of the data to prevent further spread of the etiological agent. This may include providing vaccine or immune globulin to contacts of known cases; recalling, embargoing, or destroying food; making a public announcement of the outbreak; closing a restaurant until corrections can be made; recommending antibiotic treatment and/or exclusion (from work, child care etc.) of symptomatic cases; or the use of barrier precautions such as masks and gloves; or other measures.
   - See the following references for assistance:
     - Chin, James, ed. Control of Communicable Diseases Manual (CCDM), 17th ed. Washington, D.C.: American Public Health Association, 2000
     - American Academy of Pediatrics, In: Pickering, L.K., ed 2000 Red Book: Report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL. 2000
     - Section 30.6: Guidelines for Screening and Management of Food Service Workers in Foodborne Outbreaks
     - Section 30.10: Guidelines for a Public Announcement of Exposure During a Disease Outbreak

9. Evaluate the control measures for efficacy.

- Determine if solution(s) specified in control plan are being achieved.
  - ♦ **Yes** ®
    - Consider solution(s) have been achieved if additional cases are prevented.
  - ♦ **No** ®
    - Identify problem(s), develop new solution(s), implement and evaluate.

10. Prepare report of investigation.

The final report is an important document that summarizes the outbreak. Without reliable complete information the trends in food-borne disease incidence and causal factors of the disease are difficult to determine. Good surveillance is essential for detecting and evaluating new food-borne diseases and risks.

The outbreak report should contain the following components:

- Summary (similar to an abstract)
- Introduction
- Background information
- Methods
- Results
- Analysis or interpretations
- Conclusions (optional)
- Control measures
- Recommendations

The final outbreak report may also be used to justify resources that were expended and/or to identify a need for additional resources for future incidents. The final report is a public document and may serve as evidence in legal proceedings. When the final report is completed and submitted, interim documents and working notes and other materials that are not specifically medical records can be discarded.

The final report should be completed and submitted to the District Communicable Disease Coordinator within 90 days of the conclusion of the outbreak investigation.

11. Distribute final (approved) report to all contributors and users.

12. Conduct after-action evaluation.

- Include all team members in the evaluation process.

Special circumstances:

Release of Information and Public Notification:

In some instances, the public or the press may want details of the investigation before it has been completed. Generally speaking this is to be avoided, since the investigation is a process of discovering facts, and until it is complete, all the facts may not be known. However, Section 30.3 "Criteria for Releasing Information During an Investigation" has been developed as policy for the SCDC/VPH in this situation.

Section 30.10 "Guidelines for a Public Announcement of Exposure During a Disease Outbreak" provides guidance for release of information in the situation in which there may be continuing risk to the public.

Exclusion of Food Workers:

Section 30.6 "Guidelines for Screening and Management of Food Service Workers in Foodborne Outbreaks" provides guidance for testing, and exclusion from work for food workers during outbreaks.

Multi-State Outbreaks:

Because food distribution may occur over a wide geographical area, outbreaks may affect multiple states. Section 30.12 "FDA Guidelines for Coordinating Multi-State Foodborne Outbreak Investigations" provides recommendations for these types of investigations.

Reporting Requirement

Outbreaks are a Category I disease and shall be reported to the local health authority or to the Missouri Department of Health and Senior Services (DHSS) within 24 hours of first knowledge or suspicion by telephone, facsimile or other rapid communication.

1. All outbreaks or "suspected" outbreaks must be reported as soon as possible (by phone, fax or e-mail) to the District Communicable Disease Coordinator. This can be accomplished by completing the Missouri Outbreak Surveillance Report (CD-51).
2. Within 90 days from the conclusion of an outbreak, submit the final outbreak summary to the District Communicable Disease Coordinator.

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF COMMUNICABLE DISEASE CONTROL AND VETERINARY PUBLIC HEALTH

MISSOURI OUTBREAK SURVEILLANCE REPORT

ID	OUTBREAK NAME	ENTRY DATE

PERSON RECEIVING REPORT

REPORT DATE

REPORTED BY: (check 2-digit code)

- ☐ 01 Local Health Dept
- ☐ 02 District Office
- ☐ 03 Hospital
- ☐ 04 Laboratory (non-hospital lab)
- ☐ 05 Nursing Home/Long Term Care
- ☐ 06 Child Care
- ☐ 07 School/College
- ☐ 08 Industry Worksite
- ☐ 09 Private Physician/Health Care Provider
- ☐ 10 Private Citizen
- ☐ 11 Other State Agency
- ☐ 12 Other, specify _____

DATE OF REPORT TO LOCAL HEALTH AGENCY

EVENT DESCRIPTION: (check 2-digit code)

- ☐ 01 Outbreak or possible outbreak
- ☐ 02 Case Report
- ☐ 03 Toxic Exposure
- ☐ 04 Cluster of Events
- ☐ 05 Sensitive Event
- ☐ 06 Artifact (false alarm)
- ☐ 07 Other, specify _____

CRITICAL EVENT DATE

Number of persons reported ill: _____ Attack Rate: _____

Number of persons hospitalized: _____

Number of reported deaths: _____

Estimated number of persons exposed/at risk: _____

SUSPECTED LOCATION OF EXPOSURE

- ☐ In state County _____
- ☐ Out of State State _____
- ☐ Out of Country Country _____

GENERAL CATEGORY: (check 2-digit code)

- ☐ 01 Infectious Disease
- ☐ 02 Special Syndrome (Reye, TSS, HUS, GBS)
- ☐ 03 Injury/Trauma
- ☐ 04 Chronic Disease
- ☐ 05 Environmental Hazard (noninfectious)
- ☐ 06 Occupational Hazard (noninfectious)
- ☐ 07 Other, specify _____
- ☐ 08 Unknown

SUSPECT MODE OF TRANSMISSION: (check 2-digit code)

- ☐ 01 Food
- ☐ 02 Water
- ☐ 03 Vector
- ☐ 04 Air
- ☐ 05 Person-to-Person
- ☐ 06 Medical Procedure/Medication
- ☐ 07 Environmental Exposure
- ☐ 08 Worksite Exposure
- ☐ 09 Other, specify _____

WHAT IS THE SPECIFIC SUSPECT VEHICLE (PRODUCT) OR VECTOR?

_____

_____

_____

EXPOSURE SETTING/POPULATION AT RISK: (check 2-digit code)

- ☐ 01 Camp
- ☐ 02 Childcare
- ☐ 03 Church/Temple
- ☐ 04 Club/Health Spa
- ☐ 05 Disaster (natural or man-made)
- ☐ 06 General Community
- ☐ 07 Home/Private Gathering
- ☐ 09 Immigrant/Alien
- ☐ 10 Military Base/Camp
- ☐ 12 Occupational/Workplace
- ☐ 14 Resort/Hotel
- ☐ 15 Restaurant/Food Service
- ☐ 16 School/College
- ☐ 17 Catered Event
- ☐ 18 Institution/Prison
- ☐ 19 Healthcare Facility/Hospital/Clinic/ Medical Care Site/Nursing Home/ Long Term Care
- ☐ 88 Other, specify
- ☐ 99 Unknown

SPECIFIC CAUSE: (check 3 digit code)

- ☐ 151 AGI*
- ☐ 056 AIDS
- ☐ 104 Amebiasis
- ☐ 217 ARI**
- ☐ 001 Aseptic Meningitis
- ☐ 152 Bacillus Cerus
- ☐ 053 Botulism, foodborne
- ☐ 002 Brucellosis
- ☐ 102 Campylobacteriosis
- ☐ 003 Chickenpox
- ☐ 153 Ciguatoxin
- ☐ 154 C. perfringens
- ☐ 155 Cryptosporidiosis
- ☐ 004 Diphtheria
- ☐ 156 E. coli O157:H7
- ☐ 005 Encephalitis, primary
- ☐ 218 Fifth Disease
- ☐ 157 Giardiasis
- ☐ 029 Gonorrhea
- ☐ 011 Hepatitis A
- ☐ 010 Hepatitis B
- ☐ 777 Environmental hazard or toxin: specify _____
- ☐ 888 Other, specify _____
- ☐ 999 Unknown
- ☐ 048 Hepatitis, NANB
- ☐ 012 Hepatitis (unspecified)
- ☐ 106 Influenza
- ☐ 049 Legionellosis
- ☐ 038 Hansen Disease (Leprosy)
- ☐ 039 Leptospirosis
- ☐ 158 Listeriosis
- ☐ 108 Lyme Disease
- ☐ 013 Malaria
- ☐ 050 Measles (indigenous)
- ☐ 051 Measles (imported)
- ☐ 016 Meningococcal infection
- ☐ 018 Mumps
- ☐ 555 Norwalk-Like Virus
- ☐ 019 Pertussis
- ☐ 044 Plague
- ☐ 041 Polio, (paralytic)
- ☐ 045 Psittacosis
- ☐ 159 Pseudomonas
- ☐ 034 Rabies (animal)
- ☐ 046 Rabies (human)
- ☐ 103 Reye Syndrome
- ☐ 105 Rheumatic Fever
- ☐ 025 Rocky Mtn Spotted Fever
- ☐ 020 Rubella
- ☐ 100 Salmonella, serotype: _____
- ☐ 225 Scabies
- ☐ 160 Scombrotoxin
- ☐ 101 Shigellosis
- ☐ 200 Silicosis
- ☐ 161 S. Aureus
- ☐ 219 S. Aureus - MRSA***
- ☐ 162 Strep group A
- ☐ 032 Syphilis
- ☐ 021 Tetanus
- ☐ 052 Toxic Shock Syndrome
- ☐ 027 Trichinosis
- ☐ 022 Tuberculosis
- ☐ 023 Tularemia
- ☐ 024 Typhoid Fever
- ☐ 026 Typhus (murine)
- ☐ 047 V. cholerae - 01
- ☐ 226 V. cholerae non-01
- ☐ 163 V. parahaemolyticus

*** Acute Gastrointestinal Illness of unknown etiology**
**** Acute Respiratory Illness of unknown etiology**
***** Methicillin Resistant S. aureus**

LEVEL OF INVESTIGATION BY LOCAL AGENCY:

- ☐ 01 Received Report
- ☐ 02 Handled by other person/office/agency
- ☐ 03 Consultation is provided by phone or mail
- ☐ 04 Onsite visit or assistance
- ☐ 05 Primary responsibility for investigation
- ☐ 06 Referred to District Office

Responsible agency: _____

TO BE COMPLETED BY DISTRICT HEALTH OFFICE

DISTRICT

LEVEL OF INVESTIGATION

- ☐ 01 Received Report
- ☐ 02 Handled by other person/office/agency
- ☐ 03 Consultation is provided by phone or mail
- ☐ 04 Onsite visit or assistance
- ☐ 05 Primary responsibility for investigation
- ☐ 06 Referred to the SCDCVPH

STATUS OF REPORT: Check one: ☐ **Provisional** ☐ **Closed** ☐ **Final** (A summary/writeup must be included.)

COMMENTS:

FORM COMPLETED BY | DATE

Criteria for Releasing Information During An Investigation

The Section of Communicable Disease Control and Veterinary Public Health will reveal the name of a food-service operation or facility investigated due to a foodborne or waterborne outbreak only if:

1. There is an epidemiologic association between the cases and a food service operation.

   And

   There is an ongoing risk of foodborne or waterborne disease to the public because factors related to transmission have not been eliminated.

   OR

2. There is a means to provide prophylaxis to prevent foodborne or waterborne hepatitis A and it can be administered within the effective time period.

   And

   The conditions, identified by the Centers for Disease Control and Prevention, concerning administration of IG following hepatitis A exposure have been met for public notification.

   OR

3. There is a request for release of information regarding an outbreak and its source, or a restaurant, food service establishment, or function where food was served.

   And

   The investigation is complete.

Criteria for Submitting Clinical Laboratory Specimens

Summary of Transport of Clinical Specimens *

Organism	Specimen	Transport Conditions **
Bacillus cereus	feces	Cold, no transport media
Bacillus cereus	vomitus	Cold, no transport media
Campylobacter	feces	Cold, enteric transport media (Cary-Blair)
Clostridium perfringens	feces	Cold or frozen, no transport media
Cryptosporidium	feces	Room temp, PVA and Formalin preservative
E. coli O157	feces	Cold, enteric transport media (Cary-Blair)
Giardia	feces	Room temp, PVA and formalin preservative
Norwalk-like virus (Human Calicivirus)	feces	Cold, no transport media
Salmonella	feces	Cold, enteric transport media (Cary-Blair)
Shigella	feces	Cold, enteric transport media (Cary-Blair)
Staphylococccus	feces	Cold, enteric transport media (Cary-Blair)
Staphylococcus	vomitus	Cold, no transport media
Vibrio	feces	Cold, enteric transport media (Cary-Blair)
Viruses	feces	Cold, no transport media
Yersinia	feces	Cold, enteric transport media (Cary-Blair)

Requests for isolation of more than one organism from a single clinical specimen can be made if transport conditions are comparable. However, local personnel should make every effort to determine probable causative organisms before laboratory work is requested. Culture and isolation cannot be performed on specimens submitted in PVA and formalin, and parasitology examinations cannot be performed on specimens submitted in enteric transport media.

Summary of Collection and Transport of Food Samples

Suspect foods must be transported COLD/FROZEN to the laboratory in the most expedient manner. Foods are held under similar temperature conditions for transport as at the time of sampling (i.e., hot, room temperature or cold samples transported COLD; frozen samples transported FROZEN).

*All forms must be properly and completely filled out, including collection date. All specimen vials must be labeled with patient name. Unlabeled specimen vials will NOT BE TESTED. Labeling the mailer box with the patient name is not acceptable; the specimen vials must have patient name on them.

**Specific directions for collection and transport of specimens are listed on the following pages by organism. Reading and adhering to these directions will have a direct bearing on test results. Please check specifics before sample collection is begun.

Guidelines for Investigation of Gastrointestinal Illness of Unknown Etiology

Following the initial contact concerning an outbreak of gastrointestinal illness, the health professional will be faced with a myriad of tasks to be performed before definite decisions can be made as to what laboratory test to request. The following protocol should be followed.

Stool samples will be collected from all symptomatic individuals (no more than 72 hours from onset). Two samples will be collected; one with transport media (for bacterial testing) and one without transport (for viral and certain bacterial testing). If initial collections must be made before outbreak supplies are available, the regular enteric outfits may be used by pouring the transport media out of one vial and marking that vial with a large X on top. No bloods will be collected at this point for Norwalk-like Virus. The State Public Health Laboratory (SPHL) will set up an outbreak kit that will include the following per patient:

1. One set of collection vials (one with and one without transport media).
2. Two patient forms (one for viral testing and one for bacterial testing).
3. One outbreak bag (with side pocket for both forms).
4. Patient instructions/institutional instructions.
5. Individual/multi mailer with cold packs and labels

After specimens are received in the laboratory, the following approach will be taken:

1. Symptoms and epidemiological data indicate illness of viral origin – all specimens (without transport media) will be tested for Norwalk-like virus, rotavirus, and adenovirus. Specimens for viral testing must be submitted to the SPHL within 72 hours of onset. A minimum of 10% of the symptomatic patients will be screened for bacterial organisms; Salmonella, Shigella, Campylobacter, Yersinia, and E. coli O157:H7. (Possibility of adding other organisms with consultation).

2. Symptoms and epidemiological data indicate illness of bacterial origin – all specimens (in transport) will be tested for Salmonella, Shigella, Campylobacter, Yersinia, and E. coli O157:H7 unless possible causative organisms can be narrowed by symptoms. A minimum of 10% of the symptomatic patients will be screened for rotavirus and adenovirus.

If any of the 10% screening (bacterial or viral) turns up positive, the rest of the patient samples will be tested for that specific organism.

If the field person is unable to determine if the suspected causative agent is bacterial or viral, the laboratory will run the specimens for both viral and bacterial agents in consultation with the Section of Communicable Disease Control and Veterinary Public Health. (If the number of specimens is very large, the Section and the SPHL may decide a certain percentage to be screened initially.)

*Additional information on specific organisms can be found throughout this manual.

Guidelines for Submission of Food Samples for Bacteriological Analysis in Outbreaks

Laboratory results and their interpretation are only as valid as the sample submitted for examination. Inappropriate samples, samples that have been improperly collected or mishandled, and unrepresentative samples will yield meaningless results. Not only must the health and welfare of the public be considered, but there is also the distinct possibility that legal action may arise from virtually any consumer complaint requiring laboratory personnel to testify concerning the results of their examinations. If the record of the sample collection is incomplete, or if samples are received in nonsterile containers or in a partially decomposed state, the laboratory results may be of little or no value.

Adequate precautions should be taken to preclude microbial contamination of samples from external sources, the air environment, sample containers, sampling devices, and improper handling, especially at temperatures that may alter significantly the microflora present. Ample refrigeration must be provided to prevent destruction or growth of organisms in the sample.

The State Public Health Laboratory recommends these general points for obtaining acceptable food samples.

1. Samples of freshly prepared foods, perishable foods or leftovers from meals implicated in an outbreak should be collected as soon as possible after report of the incident.

2. Notify the Environmental Bacteriology Unit, (573) 522-1685 or 751-7243, in advance regarding the number of samples collected, when they should arrive and the tests desired. This is necessary to assure adequate quantities of the appropriate media. Some media require several hours of preparation.

3. Whenever possible, an unopened container from the same production lot as the suspected food should be submitted.

4. If the products are in bulk form or in containers of a size impractical for submission, aseptically transfer a representative sample portion (at least 100 grams, 100 ml or 4 ounces) to a sterile container. For large solid food samples (frozen or unfrozen), test portions should be taken aseptically from several areas using sterile knives and forceps, then mixed as a composite, so that a sample more representative of the food can be evaluated. Sterile water bottles may be used to collect food samples.

5. Aseptic techniques should always be used to obtain samples even if the foods have been grossly mishandled.

6. Seal samples securely so they will not spill or open in transit to the laboratory. If the sample is to be examined for a regulatory purpose, the sample container must be sealed so that it cannot be opened without breaking the seal.

7. Cool samples in ice to 0^{o}- 4^{o} C and transport them in a sample chest with suitable refrigerant capable of maintaining the sample at 0^{o}- 4^{o} C until arrival at the laboratory. Collect frozen samples in pre-chilled containers. **DO NOT THAW SAMPLES THAT ARE ALREADY FROZEN: KEEP THEM FROZEN.**

8. Samples should be delivered to the laboratory as rapidly as possible. When it is not possible to hand-deliver samples to the laboratory; they should be shipped by the most rapid method.

9. A separate Food and Drug Specimen Information and Flow Sheet (Lab-52) must be properly and completely filled out for each sample. One completed reverse side is sufficient for each series of samples.

10. The District Communicable Disease Coordinator can assist in facilitating shipment of food samples for bacteriological analysis if needed.

If there is a question as to the integrity of the leftover food from the suspect meal(s), samples may be collected and the situation discussed with the Environmental Bacteriology Unit. Compromised samples may be analyzed for a specific organism only if that organism has already been isolated from clinical specimens collected in an outbreak investigation.

The SPHL's testing protocol has included a standard plate count in addition to specific bacterial analyses for food samples. However, for foods prepared with cultured products, cheese, sour cream, etc., a standard plate count and direct microscopic examination will not be performed. Presence of coliform organisms and/or yeast and mold would be appropriate indicators of mishandling.

Samples submitted directly to us by the public will not be accepted for analysis.

For further information regarding the submission of food samples, please contact the Environmental Bacteriology Unit (573 / 522-1685 or 751-7243).

Guidelines For Screening And Management Of Food Service Workers In Foodborne Outbreaks

Organism Unknown

Exclusion. All foodhandlers in the implicated establishment who have symptoms similar to the outbreak cases should be immediately excluded from foodhandling duties. They should not return to foodhandling until their symptoms resolve, or if the causative organism is identified, until the disease-specific guidelines below are met.

Epidemiologic investigation. Conduct a thorough investigation (See Section 30.0). Determine the predominant symptoms, their duration and the incubation period. Develop a hypothesis regarding the causative organism. Then follow the disease-specific guidelines below.

Bacillus Cereus
Clostridium Perfringens
Vibrio Parahemolyticus

Transmission. Not usually transmitted from person to person.

Exclusion. Exclude ill persons from handling food while symptomatic.

Screening. Collect one fecal specimen from each ill worker within the appropriate time frame (24 hours for V. parahemolyticus, 3 days for B. cereus and C. perfringens). No screening of asymptomatic foodhandlers is necessary.

Management. Employees may return to work when no longer symptomatic. No follow-up culturing is necessary.

Staphylococcal Food Poisoning

Transmission. May be transmitted by infected or colonized foodhandlers.

Exclusion. Exclude ill persons from handling food while symptomatic. Exclude foodhandlers with boils, abscesses and other purulent lesions of the hands, face or nose until lesions are healed.

Screening. Collect one feces or vomitus specimen from each foodhandler with gastrointestinal symptoms within 24 hours of onset. Specimens should be obtained from any purulent lesions, using culturettes.

If fecal specimens from cases and samples of implicated foods are not available, nasal cultures of foodhandlers may be considered. This should be done only after consultation with the Section of Communicable Disease Control and Veterinary Public Health and the SPHL Microbiology Unit.

Management. Employees may return to work when no longer symptomatic. No follow-up culturing is necessary. Proper personal hygiene should be stressed.

Campylobacter Enteritis

Transmission. Person-to-person transmission is possible but infrequent.

Exclusion. Exclude ill persons from handling food while symptomatic.

Screening. Collect one stool specimen from each foodhandler for case finding purposes. Rectal swabs are not recommended.

Management. Employees may return to work when no longer symptomatic. Antibiotic treatment is recommended to shorten the duration of excretion. No follow-up culturing is necessary. Give instructions in good handwashing after defecation and proper foodhandling procedures.

Salmonella

Transmission. May be transmitted from infected foodhandlers, with or without symptoms.

Exclusion. Exclude ill persons from handling food immediately. Exclude asymptomatic persons with positive stool cultures immediately.

Screening. Collect two stool specimens, at least 24 hours apart, from each foodhandler for screening. Rectal swabs are not recommended.

Management. Both cultures negative: No additional culturing is necessary. If symptomatic, continue to exclude from foodhandling until symptoms resolve. Give instructions in good handwashing after defecation and proper foodhandling procedures.

Culture positive (one or both): Continue to exclude from foodhandling until follow-up cultures indicate worker is no longer infected. Antibiotic therapy is not usually recommended, as it may prolong the period of excretion. After symptoms resolve, worker may be assigned to non-foodhandling duties. This should be encouraged, since excretion may last up to several months.

Follow-up cultures should be done as follows: Wait one week after initial specimens. Take two stool specimens, at least 24 hours apart. If both are negative, worker may return to foodhandling duties. If one or both stools are positive, wait one week and take two more specimens, 24 hours apart. Repeat this procedure weekly until both specimens are negative.

Give instructions in good handwashing after defecation and proper foodhandling procedures.

Shigella

Transmission. May be transmitted from infected foodhandlers, with or without symptoms.

Exclusion. Exclude ill persons from handling food immediately. Exclude asymptomatic persons with positive stool cultures immediately.

Screening. Collect two stool specimens, at least 24 hours apart, from each foodhandler for screening. Rectal swabs are not recommended.

Management. Both cultures negative: No additional culturing is necessary. If symptomatic, continue to exclude from foodhandling until symptoms resolve. Give instructions in good handwashing after defecation and proper foodhandling procedures.

Culture positive (one or both): Continue to exclude from foodhandling until follow-up cultures indicate worker is no longer infected. Appropriate antibiotic treatment can shorten the duration of illness and of positive cultures.

Follow-up cultures should be done as follows: if not treated with antibiotics, wait one week after initial specimens. If treated with antibiotics, wait at least 48 hours after dose is taken. Take stool specimens at least 24 hours apart. If both are negative, worker may return to foodhandling duties. If one or both stools are positive, wait one week and take two more specimens, 24 hours apart. Repeat this procedure weekly until both specimens are negative.

Give instructions in good handwashing after defecation and proper foodhandling procedures.

Viral Gastroenteritis

Transmission. May be transmitted by infected foodhandlers.

Exclusion. Exclude ill persons from handling food immediately.

Screening. Collect one stool specimen from each symptomatic foodhandler for testing.

Management. Employees may return to work when no longer symptomatic. No follow-up testing is necessary. Give instructions in good handwashing after defecation and proper foodhandling procedures.

Table B. *Illnesses acquired by ingestion of contaminated foods: A condensed classification by symptoms, incubation periods, and types of agents*

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
UPPER GASTROINTESTINAL TRACT SIGNS AND SYMPTOMS [NAUSEA, VOMITING] PREDOMINATE Incubation (latency) period usually less than 1 hour						
			Fungi			
Gastrointestinal irritating group mushroom poisoning	Possibly resin-like substances in some mushrooms (mushroom species are different from those cited on pages *** and ***)	30 min to 2 h	Nausea, vomiting retching, diarrhea, abdominal pain	Many varieties of wild mushrooms	Vomitus	Eating unknown varieties of wild mushrooms; mistaking toxic mushrooms for edible varieties
			Chemicals			
Antimony poisoning	Antimony in gray enamelware	Few min to 1 h	Vomiting, abdominal pain, diarrhea	High-acid foods and beverages	Vomitus, stools, urine	Purchasing/using antimony-containing utensils; storing high-acid foods in chipped gray enamelware

Cadmium poisoning	Cadmium in plated utensils	15-30 min	Nausea, vomiting abdominal cramps, diarrhea, shock	High-acid foods and beverages; metal-colored cake decorations	Vomitus, stools, urine, blood	Purchasing/using cadmium-containing utensils; storing high-acid beverages in cadmium containers
Copper poisoning	Copper in pipes and utensils; old ice cream machines; old dairy white metal	Few min to few h	Metallic taste, nausea, vomiting (green vomitus), abdominal pain diarrhea, chills	High-acid foods and ice cream (ices) and beverages	Vomitus, gastric washings, urine, blood	Faulty backflow preventors in vending machines or soda fountains; storing or vending high-acid (low pH) beverages from copper containers, pipe lines, or old equipment containing copper

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Fluoride poisoning	Sodium fluoride in insecticides and rodenticides	Few min to 2 h	Salty or soapy taste, numbness of mouth, vomiting, diarrhea, dilated pupils, spasms, pallor, shock, collapse	Any accidentally-contaminated foods, particularly dry foods (such as dry milk, flour, baking powder, cake mixes)	Vomitus, gastric washing	Storing insecticides in same area as foods, mistaking pesticides for powdered foods

Lead poisoning	Lead in earthenware vessels; pesticides, paint, plaster, putty, soldered joints	30 min or longer	Metallic taste, burning of mouth, abdominal pain, milky vomitus, bloody or black stools, foul breath, blue gum line, shock	High-acid foods and beverages stored in lead-containing vessels; any accidentally contaminated food	Vomitus, gastric washing, stools, blood, urine	Purchasing or using lead-containing vessels; storing high-acid foods including wine in lead-containing vessels; storing pesticides in same area as food
Tin poisoning	Tin in tinned cans or containers	30 min to 2 h	Bloating, nausea, vomiting, abdominal cramps, diarrhea, headache	High-acid foods and beverages	Vomitus, gastric washing, urine, blood, stools	Storing high-acid foods in tinned cans or containers in which there is no lacquer or the lacquer had peeled. Very high concentrations are required to cause illness
Zinc poisoning	Zinc in galvanized containers	Few min to few h	Pain in mouth and abdomen, nausea, vomiting, dizziness	High-acid foods and beverages	Vomitus, gastric washing, urine, blood, stools	Storing high-acid foods in galvanized cans

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Incubation (latency) period usually between 1 and 6 h						
Bacteria						
Bacillus cereus gastroenteritis	Exo-enterotoxin of *B. cereus*; organism in soil (strains differ from those cited on page ***)	½ to 5 h	Nausea, vomiting, occasionally diarrhea	Boiled or fried rice, cooked cornmeal dishes, porridge, pasta	Vomitus, stool	Storing cooked foods at room temperature; storing cooked foods in large containers in refrigerator; preparing foods several hours before serving
Staphylococcal intoxication	Exoenterotoxins A, B, C, D, E, F, or H of *Staphylococcus aureus.* Staphylococci from nose, skin and lesions of human beings and other animals and from udders of cows	1 to 8 h, typically 2 to 4 h	Nausea, vomiting retching, abdominal pain, diarrhea, prostration	Ham, meat and poultry products; cream-filled pastries; whipped butter; cheese; dry milk; food mixtures; high protein leftover foods	Ill: vomitus stools, rectal swabs. Food handlers: nasal swabs, swabs of lesions	Storing cooked foods at room temperature; storing cooked foods in large containers in refrigerator; touching cooked foods; preparing foods several hours before serving; holding foods at warm bacterial-incubation temperatures; fermentation of abnormally low-acid foods; handling foods by persons with pus-containing infections

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
			Chemicals			
Nitrite poisoning[c]	Nitrites or nitrates used as meat curing compounds	1 to 2 h	Nausea, vomiting, cyanosis, headache, dizziness, weakness; loss of consciousness; chocolate-brown colored blood[c]	Cured meats; any accidentally-contaminated food; spinach excessive nitrification	Blood	Using excessive amounts of nitrites or nitrates in foods for curing or for covering up spoilage; mistaking nitrites for common salt and other condiments; improper refrigeration of fresh produce; excessive nitrification of fertilized foods
Diarrhetic shellfish poisoning	Okadaic acid and other toxins produced by dinoflagellates *Dinophysis* spp.	½ to 12 h, usually 4 h	Diarrhea, nausea, vomiting, abdominal cramps, chills	Mussels, clams, scallops	Gastric washing	Harvesting shellfish from waters with higher than usual concentration of *Dinophysis* spp.
			Incubation (latency) period usually between 7 and 12 h			
			Fungi			
Cyclopeptide and gyromitrin groups of mushroom poisoning	Cyclopeptides and gyromitrin in some mushrooms (mushroom species are different from those cited on pages *** and ***)	6 to 12 h	Abdominal pain, feeling of fullness, vomiting, protracted diarrhea, loss of strength, thirst, muscle cramps, collapse, jaundice, drowsiness, dilated pupils, coma; death	*Amanita phalloides, A.verna, Galerina autumnalis, Gyromitra esculenta* (false morels) and similar species of mushrooms	Urine, blood, vomitus	Eating certain species of *Amanita, Galerina,* and *Gyromitra* mushrooms; eating unknown varieties of mushrooms; mistaking toxic mushrooms for edible varieties

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Incubation (latency) period between 13 and 72 h						
Viruses						
Small round structured virus gastroenteritis	Norwalk, Hawaii, Snow Mountain, Taunton Viruses: Caliciviruses	½ to 3 days, typically 36 hours	Nausea, vomiting, diarrhea, abdominal pain, myalgia, headache, malaise, low-grade fever; duration 36 hours	Human feces	Stools, acute and convalescent blood	Infected persons touching ready-to-eat foods; harvesting shellfish from sewage polluted waters; inadequate sewage disposal; using contaminated water
BURNING MOUTH, SORE THROAT AND/OR RESPIRATORY SYMPTOMS AND SIGNS OCCUR						
Incubation period less than 1 h						
Chemicals						
Calcium chloride poisoning	Calcium chloride freezing mixture for frozen dessert bars	Few min	Burning lips, mouth, throat; vomiting	Frozen dessert bars	Vomitus	Splashing of freezing mixture onto popsicles while freezing; cracks in molds allowing $CaCl_2$ to penetrate popsicle syrup
Sodium hydroxide poisoning	Sodium hydroxide in bottle-washing compounds, detergents, drain cleaners, or hair straighteners	Few min	Burning of lips, mouth and throat; vomiting, abdominal pain, diarrhea	Bottled beverages, pretzels	Vomitus	Inadequate rinsing of bottles cleaned with caustic soda; inadequate baking of pretzels

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Incubation (latency) period usually between 18 and 72 h						
Bacteria						
Beta-hemolytic streptococcal infections	*Streptococcus pyogenes* from throat and lesions of infected humans	1 to 3 days	Sore throat, fever, nausea, vomiting, rhinorrhea; sometimes a rash. Sequela: rheumatic fever	Raw milk, egg-containing salads	Throat swabs, vomitus	Persons touching cooked foods; touching of foods by persons with pus-containing infections; room-temperature storage; storing cooked foods in large containers in refrigerator; inadequate cooking or reheating; preparing foods several hours before serving
LOWER GASTROINTESTINAL TRACT SIGNS AND SYMPTOMS [ABDOMINAL CRAMPS, DIARRHEA] PREDOMINATE						
Incubation (latency) period usually between 7 and 17 h						
Bacteria						
Bacillus cereus enteritis	Enterotoxins of *B. cereus*. Organisms in soil (strains differ from those cited in page **)	8 to 16 h, mean 12 h	Nausea, abdominal pain, watery diarrhea	Cereal products, soups, custards and sauces, meatloaf, sausage, cooked vegetables, reconstituted dried potatoes, refried beans	Stools	Storing cooked foods at room temperature; storing cooked foods in large containers in refrigerator; holding foods at warm (bacterial-incubating) temperatures; preparing foods several hours before serving; inadequate reheating of leftovers

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Clostridium perfringens enteritis	Endoenterotoxin formed during sporulation of *C. perfringens* in intestines; organism in feces of humans, other animals, and in soil	8 to 22 h, typically 10 h	Abdominal pain, diarrhea	Cooked meat, poultry, gravy, sauces, meat-containing soups, refried beans	Stools	Storing cooked foods at room temperature; storing cooked foods in large containers in refrigerators; holding foods at warm (bacterial-incubating) temperatures; preparing foods several hours before serving; inadequate reheating of leftovers
Incubation (latency) period usually between 18 and 72 h						
Bacteria						
Aeromonas diarrhea	*Aeromonas hydrophila*	1 to 2 days	Water diarrhea, abdominal pain, nausea, chills, headache	Fish, shellfish, snails, water	Stools	Contamination of foods by sea or surface water
Campylobacteriosis	*Campylobacter jejuni*	2 to 7 days, usually 3 to 5 days	Abdominal cramps, diarrhea (blood and mucus frequently in stools), malaise, headache, myalgia, fever, anorexia, nausea, vomiting. Sequela: Guillain-Barre syndrome	Raw milk, poultry, beef liver, raw clams, water	Stools, rectal swabs, blood	Drinking raw milk; handling raw poultry; eating raw or rare meat or poultry; inadequate cooking or pasteurization; cross contamination from raw meat

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Cholera	*Vibrio cholerae* serogroup O1 classical and El Tor biotypes; serogroup O139	1 to 5 days, usually 2 to 3 days	Profuse watery diarrhea (rice-water stools), vomiting, abdominal pain, rapid dehydration, thirst, collapse, reduced skin turgor, wrinkled fingers, sunken eyes, acidosis	Raw fish, raw shellfish, crustacea; foods washed or prepared with contaminated water; water	Stools, rectal swabs	Obtaining fish and shellfish from sewage-contaminated waters in endemic areas, poor personal hygiene, infected persons touching foods, inadequate cooking, using contaminated water to wash or freshen foods, improper sewage disposal, using night soil as fertilizer
Cholera-like vibrio gastroenteritis	Non O-1/O139 *V. cholerae* and related spp. (e.g., *V. mimicus, V. fluvialus, V. hollisae*)	1 to 5 days	Watery diarrhea (varies from loose stools to cholera-like diarrhea)	Shellfish, fish	Stools, rectal swabs	Obtaining fish and shellfish from sewage-contaminated waters; inadequate cooking; cross contamination
Enterohemorrhagic or verotoxigenic *Escherichia coli* diarrhea	*E. coli* O157:H7, O26, O111, O115, O113	1 to 10 days, typically 2 to 5 days	Watery diarrhea, followed by bloody diarrhea; severe abdominal pain; blood in urine. Sequela: hemolytic uremic syndrome	Hamburgers, raw milk, roast beef, sausages, apple cider, yogurt, sprouts, lettuce, water	Stools, rectal swabs	Ground beef made from meat from infected cattle; ingesting raw meat or milk; inadequate cooking; cross contamination; infected persons touching ready-to-eat food; inadequately drying and fermenting meats

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Enteroinvasive *Escherichia coli* diarrhea	Enteroinvasive-*E. coli* strains	½ to 3 days	Severe abdominal cramps, fever, watery diarrhea (blood and mucus usually present), tenesmus, malaise	Salads and other foods that are not subsequently heated; soft cheeses, water	Stools, rectal swabs	Inadequate cooking; infected persons touching ready-to-eat foods; not washing hands after defecation; storing cooked foods at room temperature; storing cooked foods in large containers in refrigerators; holding foods at warm (bacterial-incubating) temperatures; preparing foods several hours before serving; inadequate reheating of leftovers
Enterotoxigenic *Escherichia coli* diarrhea	Enterotoxigenic-*E. coli* strains	½ to 3 days	Profuse watery diarrhea (blood and mucus absent), abdominal pain, vomiting, prostration, dehydration, low-grade fever	Salads and other foods that are not subsequently heated; soft cheeses, water	Stools, rectal swabs	Inadequate cooking; infected persons touching ready-to-eat foods; not washing hands after defecation; storing cooked foods at room temperature; storing cooked foods in large containers in refrigerators; holding foods at warm (bacterial-incubating) temperatures; preparing foods several hours before serving; inadequate reheating of leftovers; using raw milk for cheese making

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Plesiomonas enteritis	*Plesiomonas shigelloides*	1 to 2 days	Diarrhea (blood and mucus in stools), abdominal pain, nausea, chills, fever, headache, vomiting	Water	Stools, rectal swabs	Inadequate cooking
Salmonellosis	*Salmonella* (>2,000 serovars.) from feces of infected animals	6-72 hours, typically 18-36 h	Abdominal pain, diarrhea, chills, fever, nausea, vomiting, malaise	Poultry, eggs and meat and their products, raw milk and dairy products, other foods contaminated by salmonellae (e.g., sprouts, melons, chocolate, cereal)	Stools, rectal swabs	Storing cooked foods at room temperature; storing cooked foods in large containers in refrigerators; holding foods (including sliced melons) at warm (bacterial-incubating) temperature; inadequate cooking and reheating; preparing foods several hours before serving; cross contamination; improper cleaning of equipment; obtaining foods from contaminated sources; occasionally infected persons touching ready-to-eat foods
Shigellosis	*Shigella dysenteriae, S. flexneri, S. boydii, S. sonnei*	½ to 7 days, typically 1 to 3 days	Abdominal pain, diarrhea (stools may contain blood, pus, and mucus), tenesmus, fever, vomiting	Any ready-to-eat food contaminated by infected person; frequently salads, poi, water	Stools, rectal swabs	Infected person touching ready-to-eat foods, improper refrigeration, inadequate cooking and reheating

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Vibrio parahaemolyticus gastroenteritis	*Vibrio parahaemolyticus*	4 to 96 h, typically 12 h	Abdominal pain, diarrhea, nausea, vomiting, fever, chills, headache	Marine fish, molluscan shellfish, crustacea (raw or recontaminated)	Stool, rectal swabs	Eating raw fin fish and shellfish; inadequate cooking; improper refrigeration; cross contamination; improper cleaning of equipment; using sea water in food preparation or to cool cooked foods
Yersiniosis	*Yersinia enterocolitica, Y. pseudotuberculosis*	1 to 7 days	Abdominal pain (may simulate acute appendicitis); low-grade fever, headache, malaise, anorexia, chills, diarrhea, nausea, vomiting	Raw milk, tofu, water	Stools, rectal swabs	Inadequate cooking or pasteurization; contamination after cooking; surface or spring water as ingredients or for packing foods; cross contamination
			Viruses			
Astrovirus gastroenteritis	Astroviruses from human feces	1 to 2 days	Diarrhea, sometimes accompanied by one or more enteric signs or symptoms	Ready-to-eat foods	Stools, acute and convalescent blood	Failure to wash hands after defecation; infected person touching ready-to-eat foods; inadequate cooking or reheating
Norwalk and small round structured viral gastroenteritis	(See entry under *Upper gastrointestinal signs and symptoms predominate*, page ***)					

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Incubation Periods from a Few Days to a Few Weeks						
Parasites						
Amebiasis	*Entamoeba histolytica*	Few days to several months, typically 2 to 4 wk	Mild to severe gastroenteritis; abdominal pain, constipation or diarrhea (stools contain blood and mucus), fever, chills, skin ulcers	Raw fruit, vegetable or seafood salads	Stools, blood	Poor personal hygiene, infected persons touching ready-to-eat foods; inadequate cooking and reheating
Anisakiasis	*Anisakis, pseudoterranova*	4 to 6 wk	Stomach pain, nausea, vomiting abdominal pain, diarrhea, fever	Rock fish, herring, cod, salmon, squid, sushi	Stools	Ingestion of raw fish, inadequate cooking
Beef tapeworm infection (Taeniasis)	*Taenia saginata* from flesh of infected cattle	8 to 14 wk	Vague discomfort, hunger pains, loss of weight, abdominal pain	Raw or insufficiently cooked beef	Stools	Lack of or proper meat inspection; inadequate cooking; inadequate sewage disposal, contaminated pastures
Cyclosporosis	*Cyclospora cayetanensis*	1-11 days, typically 7 days	Prolonged watery diarrhea, weight loss, fatigue, nausea, anorexia, abdominal cramps	Raspberries, lettuce, basil, water	Stools	Sewage contaminated irrigation or spraying water suspected; washing fruits with contaminated water; possibly, handling foods that are not subsequently heated

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Cryptosporidium	*Cryptosporidium parvum*	1-12 days, usually 7 days	Profuse watery diarrhea, abdominal pain, anorexia, vomiting, low-grade fever	Apple cider, water	Stools, intestinal biopsy	Inadequate sewage or animal waste disposal; contamination by animal manure; contaminated water; inadequate filtration of water
Fish tapeworm infection (Diphyllobothriasis)	*Diphyllobothrium latum* from fresh of infested fish	5 to 6 wk	Vague gastrointestinal discomfort, anemia may occur	Raw or insufficiently cooked freshwater fish (perch, pike, turbot, trout, salmon)	Stools	Inadequate cooking; improper sewage disposal; sewage-contaminated lakes
Giardiasis	*Giardia lamblia*	5 to 25 days, typically 7 to 10 days	Diarrhea (pale, greasy, malodorous stools), abdominal pain, bloating, nausea, weakness, vomiting, dehydration, fatigue, weight loss, fever	Salmon, salads, water	Stools	No or inadequate hand washing after defecation; infected persons handling ready-to-eat foods; inadequate sewage disposal; using untreated surface water supplies as ingredient or for processing
Pork tapeworm infection (Taeniasis)	*Taenia solium* from flesh of infected swine	8 to 14 wk	Vague discomfort, hunger pains, weight loss	Raw or insufficiently cooked pork	Stools	Lack of improper meat inspection; inadequate cooking; improper sewage disposal; contaminated pastures

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
NEUROLOGICAL SYMPTOMS AND SIGNS (VISUAL DISTURBANCES, TINGLING, AND/OR PARALYSIS) OCCUR[c]						
Incubation (latency) period usually less than 1 h						
Fungi						
Ibotenic acid group of mushroom poisoning	Ibotenic acid and muscinol in some mushrooms (mushroom strains are different from those cited on pages *** and ***)	30 to 60 min	Drowsiness and state of intoxication, confusion, muscular spasms, delirium, visual disturbances	*Amanita muscaria, A. pantherina* and related species of mushrooms		Eating *A. muscaria* and related species of mushrooms; eating unknown varieties of mushrooms; mistaking toxic mushrooms for edible varieties; seeking hallucinogenic effects
Muscarine group of mushroom poisoning	Muscarine in some mushrooms (mushroom strains are different from those cited on pages *** and ***)	15 min to few h	Excessive salivation, perspiration, tearing, reduced pressure, irregular pulse, constricted pupils, blurred vision, asthmatic breathing	*Clitocybe dealbata, C. rivulosa* and many species of *Inocybe* and *Boletus* mushrooms		Eating muscarine group of mushrooms; eating unknown varieties of mushrooms; mistaking toxic mushrooms for edible mushrooms
Chemicals						
Organophosphorous poisoning	Organic phosphorous insecticides (such as parathion, TEPP, diazinon, malathion)	Few min to few h	Nausea, vomiting, abdominal cramps, diarrhea, headache, nervousness, blurred vision, chest pain, cyanosis, confusion, twitching, convulsions	Any accidentally-contaminated food	Blood, urine, fat biopsy	Spraying foods just before harvesting, storing insecticides in same area as foods; mistaking pesticides for dried foods

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Carbamate poisoning	Carbamyl (sevin), Temik (aldicarb)	½ h	Epigastric pain, vomiting, abnormal salivation, sweating, twitching, fasciculations, contractions of pupils, muscular incoordination	Watermelons, cucumbers, any accidentally-contaminated food	Blood, urine	Inappropriate application for vine foods; storing insecticides in same area as foods; mistaking pesticides for powdered foods
Paralytic/neurologic shellfish poisoning	Saxitoxin and similar toxins from dinoflagellates *Alexandrium* and *Gymnodinium* species	Few min to 30 min	Tingling, burning, numbness around lips and finger tips, giddiness, incoherent speech, difficulty standing, respiratory paralysis	Mussels, clams, scallops	Gastric washing	Harvesting shellfish from waters with high concentration of *Alexandrium* or *Gymnodinium* species (Red tides)
Tetrodotoxin (Fugu/Puffer) poisoning	Tetrodotoxin from intestines and gonads of puffer-type fish	10 min to 3 h	Tingling sensation of fingers and toes; dizziness, pallor, numbness of mouth and extremities, gastrointestinal symptoms, hemorrhage, desquamation of skin, fixed eyes, twitching, paralysis, cyanosis; fatalities occur	Puffer-type fish		Eating puffer-type fish; failure to effectively remove intestines and gonads from puffer-type fish if they are to be eaten

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
			Plant toxicants			
Jimson weed	Tropane alkaloids	Less than 1 h	Abnormal thirst, photophobia, distorted sight, difficulty speaking, flushing, delirium, coma, rapid heart beat	Any part of jimson weed; tomatoes grafted to jimson weed stock	Urine	Eating any part of jimson weed or eating tomatoes from tomato plant grafted to jimson weed stock
Water hemlock poisoning	Resin and cicutoxin in hemlock root *Cicuta virosa, C. masculate,* and *C. douglasii*	15 to 60 min	Excessive salivation, nausea, vomiting, stomach pain, frothing at mouth, irregular breathing, convulsions, respiratory paralysis	Root of water hemlock	Urine	Eating water hemlock; mistaking water hemlock root for wild parsnip, sweet potato, or carrot
			Incubation (latency) period usually between 1-6 h			
			Chemicals			
Chlorinated hydrocarbon poisoning	Chlorinated hydrocarbon insecticides	30 min to 6 h	Nausea, vomiting, parasthesia, dizziness, muscular weakness, anorexia, weight loss, confusion	Any accidentally-contaminated food	Blood, urine, stools, gastric washing	Storing insecticides in same area as food; mistaking pesticides for dried foods

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
			Marine Plankton			
Ciguatera poisoning	Ciguatoxin in fatty tissues in head and flesh of tropical marine fish. From marine plankton	3 to 5 h, sometimes longer	Gastrointestinal symptoms which disappear in a few days; tingling and numbness of mouth and limbs, muscular and joint pain, dizziness, cold-hot sensations, rash, weakness, slow heartbeat, prostration, paralysis; neurological problems may last several days; deaths occur	Numerous varieties of tropical fish, e.g., barracuda, grouper, red snapper, amber jack, goat-fish, skipjack, parrotfish		Eating fatty tissues in head flesh of tropical reef fishes; usually large reef fish are more commonly toxic. (The more toxic regions are in the South Pacific and Indian Oceans and the Caribbean Sea.)

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Incubation (latency) period usually between 12 to 72 h						
Bacteria						
Botulism	Neurotoxins A, B, E, and F of *Clostridium botulinum*; spores found in soil, freshwater mud and animals	2 h to 8 days, typically 18 to 36 h	Gastrointestinal symptoms may precede neurological symptoms. Vertigo, double or blurred vision, dryness of mouth, difficult swallowing, speaking and breathing; descending muscular weakness, constipation, dilated or fixed pupils, respiratory paralysis; fatalities occur	Canned low-acid foods (usually home canned); smoked fish; cooked potatoes; onions, garlic in oil, frozen pot pies, meat loaf, stew left overnight in ovens without heat; fermented fish eggs, fish, marine mammals, muskrat tails, seal flippers, uneviscerated fish	Blood, stool, gastric washing	Inadequate heat processing of canned foods and smoked fish; post-processing contamination, uncontrolled fermentations; improper curing of hams and fish; holding foods at room and warm temperatures

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Incubation (latency) period usually greater than 72 h						
Chemicals						
Mercury poisoning	Methyl and ethyl mercury compounds from industrial waste and organic mercury in fungicides	1 wk or longer	Numbness, weakness of legs, spastic paralysis, impaired vision, blindness, coma	Grains treated with mercury-containing fungicide; pork, fish and shellfish exposed to mercury compounds	Urine, blood, hair	Fish harvested from water polluted with mercury compounds; feeding animals grains treated with mercury fungicides; eating mercury-treated grains or meat from animals fed such grains
Triorthocresyl phosphate poisoning	Triorthocresyl phosphate used as extracts or as oil substitute	5 to 21 days, mean 10 days	Gastrointestinal symptoms, leg pain, ungainly high-stepping gait, foot and wrist drop	Cooking oils, extracts and other foods contaminated with triorthocresyl phosphate	Biopsy of gastronemisus muscle	Using compounds as food extractant or as cooking or salad oil
GENERALIZED INFECTION SIGNS AND SYMPTOMS (FEVER, CHILLS, AND/OR MALAISE) OCCUR						
Incubation period usually between 12-72 h						
Bacteria						
Vibrio vulnificus infection	*Vibrio vulnificus*	16 h	Septicemia, fever, chills, malaise, prostration; pre-existing liver disease in cases typical	Raw oysters and clams	Blood	Persons with liver ailments eating raw shellfish

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Incubation (latency) period usually greater than 1 week						
Bacteria						
Brucellosis	*Brucella abortus, B. melitensis* and *B. suis* from tissues and milk of infected animals	7 to 21 days	Fever, chills, sweating, weakness, malaise, headache, muscle and joint pain, loss of weight	Raw milk, goat cheese made from unpasteurized milk	Blood	Failure to pasteurize milk, livestock infected with brucellae
Listeriosis	*Listeria monocytogenes*	3 to 70 days, usually 4 to 21 days	Fever, headache, nausea, vomiting, stillbirths, meningitis, encephalitis, sepsis	Coleslaw, milk, soft cheese, pate, turkey franks, processed meats	Blood, urine	Inadequate cooking; failure to properly pasteurize milk; prolonged refrigeration
Typhoid or paratyphoid fevers	*Salmonella typhi* for typhoid from feces of infected humans; other serovars. (e.g., *paratyphi A, choleraesuis, enteritidis*) for paratyphoid from infected humans or other animals	7 to 28 days, usually 14 days	Continued fever, malaise, headache, cough, nausea, vomiting, anorexia, abdominal pain, chills, rose spots, constipation or bloody diarrhea. Sequela: reactive arthritis	Shellfish; any food contaminated by infected person, raw milk, post-process-contaminated meat, cheese, watercress, water	Stools, rectal swabs, blood in incubatory and early acute phase, urine in acute phase	Infected persons touching foods; failure to wash hands after defecation; inadequate cooking; improper refrigeration; improper sewage disposal; obtaining foods from unsafe sources; harvesting shellfish from sewage-contaminated waters

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
			Viruses			
Hepatitis A	Hepatitis A virus	15 to 50 days, usually 25-30	Fever, malaise, lassitude, anorexia, nausea, abdominal pain, jaundice, dark urine, light-colored stools	Raw shellfish, any food contaminated by infected person	Stools, urine, blood	Infected persons touching foods; failure to wash hands after defecation; inadequate cooking; harvesting shellfish from sewage-contaminated waters; improper sewage disposal
Hepatitis E	Hepatitis E virus	15 to 65 days, usually 35-40	Similar to above (high mortality for pregnant women)	Raw shellfish, any food contaminated by infected person	Stools, urine, blood	Infected persons touching foods; failure to wash hands after defecation; inadequate cooking; harvesting shellfish from sewage-contaminated waters; improper sewage disposal
			Parasites			
Angiostrongyliasis (eosinophilic meningo-encephalitis)	*Angiostrongylus cantonensis* (rat lung worm) from rodent feces and soil	14 to 16 days	Gastroenteritis, headache, stiff neck and back, low-grade fever	Raw crabs, slugs, prawns, shrimp, snails	Blood	Ingesting raw foods, inadequate cooking
Toxoplasmosis	*Toxoplasma gondii* from tissue and animal	10 to 13 days	Fever, headache, myalgia, rash	Raw or insufficiently-cooked beef, lamb, wild pig, venison	Biopsy of lymph nodes, blood	Ingesting raw meat, inadequate cooking

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
Trichinosis	*Trichinella spiralis* (roundworm) from flesh of infected swine, bear, walrus	4 to 28 days, mean 9 days	Gastroenteritis, fever, edema about eyes, muscular pain, chills, prostration, labored breathing	Pork, bear meat, walrus flesh; cross contaminated ground beef and lamb, often in grinders	Blood, muscle biopsy, skin test	Eating raw or inadequately cooked pork or bear meat; inadequate cooking or heat processing; feeding uncooked or inadequately heat-processed garbage to swine; failure to clean grinders between grinding pork and other meats
ALLERGIC-TYPE SYMPTOMS AND SIGNS (FACIAL FLUSHING AND/OR ITCHING) OCCUR **Incubation (latency) period usually less than 1 h** **Bacterial (and animal) agents**						
Histamine poisoning (scombroid poisoning)	Histamine-like substance produced by *Proteus* spp. and other bacteria	Few min to 1 h	Headache, dizziness, nausea, vomiting, peppery taste, burning throat, facial swelling and flushing, stomach pain, diarrhea, itching skin	Tuna, mackerel, Pacific dolphin (mahi mahi), blue-fish, cheese		Inadequate cooling; improper refrigeration of fish; improper curing of cheese

Illness	Etiologic agent and source	Incubation or latency period[a]	Signs and symptoms[a]	Foods usually involved[b]	Specimen to collect	Factors contributing to foodborne outbreaks
			Chemicals			
Monosodium glutamate poisoning	Excessive amounts of monosodium glutamate (MSG)	Few min to 1 h	Burning sensation in back of neck, forearms, chest; feeling of tightness in chest, tingling, flushing, dizziness, headache, nausea	Foods seasoned with MSG		Using excessive amounts of MSG as flavor intensifier. ONLY certain individuals are sensitive to MSG
Nicotinic acid (niacin) poisoning	Vitamin, sodium nicotinate used as color preservative	Few min to 1 h	Flushing, sensation of warmth, itching, abdominal pain, puffing of face and knees	Meat or other food in which sodium nicotinate has been added, including baby food and baked goods		Using sodium nicotinate as color preservative, improper mixing

[a] Symptoms and incubation periods will vary with the individual and group exposed because of resistance, age and nutritional status of individuals, number of organisms or concentration of poison ingested, amount of food eaten, and pathogenicity and virulence of strain of microorganism or toxicity of chemical involved. Several of the illnesses exhibit additional symptoms and have incubation periods that are shorter or longer than stated.

[b] Collect sample foods suspected as being the vehicle or contaminated with foodborne pathogens.

[c] Carbon monoxide poisoning may simulate this disease. Patients who have been in closed cars with motors running or have been in rooms with improperly vented heaters are subject to exposure to carbon monoxide.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
National Center for Infectious Diseases
Atlanta, GA 30333

WATERBORNE DISEASES OUTBREAK REPORT

This form should be used to report outbreaks of illness after consumption or use of water intended for drinking, as well as outbreaks associated with exposure (ingestion, contact or inhalation) to recreational water, **excluding** wound infections caused by water-related organisms.

CDC USE ONLY
–
__ __ __ __ __ __

Form Approved
OMB No. 0920-0004

SUBMITTED COPIES OF THIS FORM SHOULD INCLUDE AS MUCH INFORMATION AS POSSIBLE; BUT THE COMPLETION OF EVERY ITEM IS NOT REQUIRED.

1. TYPE of EXPOSURE:
- ☐ Water intended for drinking
- ☐ Recreational

2. LOCATION of OUTBREAK:
State: _____
City or Town: _____
County: _____

3. DATE of OUTBREAK:
(Date first case became ill):
Mo. ____ Day ____ Yr. ____

4. NUMBERS OF:

	Actual	Estimated
Persons exposed:		
Persons ill:		
Hospitalized:		
Fatalities:		

5. HISTORY of EXPOSED PERSONS:
Enter the no. of persons with the following symptoms:

NO. OF HISTORIES OBTAINED: ____ NO. OF INTERVIEWED PERSONS WHO WERE ILL: ____

Diarrhea (3 stools/day): _____ Diarrhea (other): No. _____ / definition Ð _____
Visible blood in stools: _____ Cramps: _____ Conjunctivitis: _____ Other, specify: _____
Vomiting: _____ Fever: _____ Otitis externa: _____ _____
Nausea: _____ Rash: _____ Cough: _____ _____

6. INCUBATION PERIOD: (HOURS)
Shortest: _____
Longest: _____
Median: _____

7. DURATION of ILLNESS: (DAYS)
Shortest: _____
Longest: _____
Median: _____

8. SPECIMENS EXAMINED from PATIENTS: (stool, vomitus, serum, etc.)

	SPECIMEN	No. PERSONS	FINDINGS
EXAMPLE	Stool	11	8 *Giardia lamblia* 3 negative

9. ETIOLOGY of OUTBREAK:

Agent (If not known enter "Unk.")	Diagnostic Certainty: Confirmed	Suspected
Pathogen:	☐	☐
Chemical:	☐	☐
Other:	☐	☐

Comments:
.....
.....
.....

10a. EPIDEMIOLOGIC DATA: (e.g., vehicle/source - specific attack rates; attack rate by quantity of vehicle consumed)

EXPOSURE (vehicle/source)	Number of Persons EXPOSED: ILL	**NOT** ILL	TOTAL	% ILL	Number of Persons **NOT** EXPOSED: ILL	**NOT** ILL	TOTAL	% ILL	ODDS RATIO (If available)	p VALUE or CONFIDENCE INTERVAL (If available)

Comments:
.....
.....
.....

10b. VEHICLE/SOURCE RESPONSIBLE: *(implicated by epidemiologic evidence in [10a])* _____

11. WATER SUPPLY CHARACTERISTICS: *(skip to question 12, if recreational exposure)*

a) TYPE OF WATER SUPPLY:
- ☐ Community or Municipal
  - ☐ City or County (Name: _____)
  - ☐ Subdivision
  - ☐ Trailer Park
- ☐ Noncommunity (does not obtain water from a community water system, but has developed/maintained its own water supply)
  - ☐ Camp, Cabin, Recreational area
  - ☐ School
  - ☐ Restaurant
  - ☐ Hotel, Motel
  - ☐ Church
  - ☐ Other: _____
- ☐ Individual household supply
- ☐ Bottled water
- ☐ Other: _____

b) WATER SOURCE: (check source that was cause of outbreak)
- ☐ Well
- ☐ River, Stream
- ☐ Lake, Pond, Reservoir
- ☐ Spring
- ☐ Other: _____
- ☐ Unknown

c) WATER TREATMENT PROVIDED: (check **all** that apply)
- ☐ No treatment
- ☐ Disinfection
  - ☐ Chlorine
  - ☐ Chlorine and Ammonia (chloramine)
  - ☐ Ozone
  - ☐ Other: _____
  - ☐ Unknown
- ☐ Coagulation and/or Flocculation
- ☐ Settling (sedimentation)
- ☐ Filtration at purification plant (**don't** include home filters)
  - ☐ Rapid sand
  - ☐ Slow sand
  - ☐ Diatomaceous earth
  - ☐ Other: _____
  - ☐ Unknown
- ☐ Other: _____
- ☐ Unknown

IF RECREATIONAL EXPOSURE, PROCEED TO QUESTION (12) AND THEN (13d), OTHERWISE PROCEED TO (13a).

12. RECREATIONAL EXPOSURE:

a) Route of Entry:

☐ Intentional ingestion ☐ Contact
☐ Accidental ingestion ☐ Inhalation

b) Type of Exposure:

☐ Swimming pool ☐ Hot Tub
☐ Lake, Pond ☐ Whirlpool
☐ River, Stream ☐ Other:_____

Describe the setting: (e.g., health spa, rafting trip, etc.)

13. FACTORS CONTRIBUTING TO WATER CONTAMINATION: (check **all** that apply)

a) AT SOURCE:

☐ Overflow of sewage ☐ Use of a back-up source of water by a water utility ☐ Other: _____
☐ Flooding, heavy rains ☐ Improper construction or location of well or spring ☐ Unknown
☐ Underground seepage of sewage ☐ Contamination through creviced limestone or fissured rock

b) AT TREATMENT PLANT:

☐ No disinfection ☐ No filtration ☐ Other: _____
☐ Temporary interruption of disinfection ☐ Inadequate filtration ☐ Unknown
☐ Chronically inadequate disinfection ☐ Deficiencies in other treatment processes

c) IN DISTRIBUTION SYSTEM:

☐ Cross connection ☐ Contamination of mains during construction or repair ☐ Other: _____
☐ Back siphonage ☐ Contamination of storage facility ☐ Unknown

d) OTHER REASONS FOR CONTAMINATION OF WATER: (include recreational exposures here)

14. WATER SPECIMENS EXAMINED: (provide information for routine samples collected **before** and **during** the outbreak investigation as well as for any special lab studies)

☐ NONE TESTED

		LABORATORY RESULTS		
ITEM	DATE	MICROBIOLOGY	DISINFECTANT RESIDUAL	TURBIDITY
EXAMPLES Tap Water	10/11/91	No coliforms	0.5 mg/L	0.1 NTU
Untreated Raw Water	11/02/91	23 fecal coliforms	Not Done	10.0 NTU
Tap Water	11/12/91	*Giardia*; 10 total coliforms per 100 ml	0	2.0 NTU

15. REMARKS: Briefly describe the unusual aspects of the outbreak and/or the outbreak investigation not covered above. Attach epidemic curve and summary report, if available.

Name of reporting agency:

_____

_____

Person completing form: (please print)

NAME: _____

TITLE: _____

TEL. NO: (_____) ___-____
area code

DATE OF REPORT: __ __ / __ __ / __ __
MO. DAY YR.

Date investigation initiated:

__ __ / __ __ / __ __
MO. DAY YR.

Note: Epidemic and laboratory assistance for the investigation of a waterborne outbreak is available upon request by the State Health Department to the Centers for Disease Control and Prevention. To improve national surveillance of outbreaks of waterborne diseases, please send a copy of this report, your internal report, and the questionnaire used in the epidemiologic investigation (if available) to:

Centers for Disease Control and Prevention
Division of Parasitic Diseases
Attention: Waterborne Disease Coordinator
4770 Buford Highway, NE, Mailstop F22
Atlanta, GA 30341-3724

FORM APPROVED
OMB NO.0920-0004

INVESTIGATION OF A FOODBORNE OUTBREAK

This form is used to report foodborne disease outbreak investigations to CDC. A foodborne outbreak is defined as the occurrence of **two or more cases** of a similar illness resulting from the ingestion of a common food in the United States. This form has **two** parts: Part 1 asks for the minimum data needed and Part 2 asks for additional information. For this investigation to be counted in the CDC annual summary, Part 1 must be completed. **We encourage you to complete as much of Part 1 and Part 2 as you can.**

CDC USE ONLY
__ __-__ __ __ __ __ __

STATE USE ONLY
_____

Part 1: Required Information

1. Location of Exposure:

State: ___ ___
☐ Multi-state exposure

County: _____
☐ Multi-county exposure

List other states/counties in Comments, bottom of this page

2. Dates:

Date first case became ill: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Date of first known exposure: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Date of last known exposure: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

3. Numbers of Cases Exposed:

Lab-confirmed cases: _____ *(A)*

Probable cases: _____ *(B)*

Estimated total ill: _____
(If greater than sum of A+B)

4. Approximate Percentage of Total Cases in Each Age Group:

<1 year: _____% 20-49 yrs: _____%

1-4 yrs: _____% ≥ 50 yrs: _____%

5-19 yrs: _____%

5. Sex: (Estimated percent of total cases)

Male: _____ %

Female: _____ %

6. Investigation Methods: (Check all that apply)

☐ Interviews of cases only
☐ Case-control study
☐ Cohort study
☐ Food preparation review
☐ Food product traceback
☐ Investigation at factory or production plant
☐ Investigation at original source (farm, marine estuary, etc.)
☐ Environment / food sample cultures

7. Implicated Food(s): (based on Reasons listed in Item 15 on page 3)

_____
_____
_____
_____
_____

☐ Could not be determined

8. Etiology: (Name the bacteria, virus, parasite, or toxin. If available, include details such as phage type, virulence factors, molecular fingerprinting, antibiogram, metabolic profile.

Etiology	**Serotype** (if avail.)	**Other Characteristics** (if avail.)

☐ Confirmed*
☐ Suspected

☐ Unknown etiology
☐ Multiple etiologies (list in Comments)

Isolated/identified from (check all that apply)
☐ Patient specimen(s)
☐ Food specimen(s)
☐ Environment specimen(s)
☐ Food Worker specimen(s)

* see criteria at http://www.cdc.gov/ncidod/dbmd/outbreak/ or MMWR2000/Vol 49/SS-1/Appendix B

9. Contributing Factors: (See list on page 2, check all that apply)

☐ Contributing factors unknown

Contamination Factor:
☐ C1 ☐ C2 ☐ C3 ☐ C4 ☐ C5 ☐ C6 ☐ C7 ☐ C8 ☐ C9
☐ C10 ☐ C11 ☐ C12 ☐ C13 ☐ C14 ☐ C15 *(describe in Comments)* ☐ N/A

Proliferation/Amplification Factor (bacterial outbreaks only):
☐ P1 ☐ P2 ☐ P3 ☐ P4 ☐ P5 ☐ P6 ☐ P7 ☐ P8 ☐ P9
☐ P10 ☐ P11 ☐ P12 *(describe in Comments)* ☐ N/A

Survival Factor (microbial outbreaks only):
☐ S1 ☐ S2 ☐ S3 ☐ S4 ☐ S5 *(describe in Comments)* ☐ N/A

Was food-worker implicated as the source of contamination? ☐ Yes ☐ No
If yes, please check ***only one*** of following:
☐ laboratory *and* epidemiologic evidence
☐ epidemiologic evidence (w/o lab confirmation)
☐ lab evidence (w/o epidemiologic confirmation)
☐ prior experience makes this the likely source *(please explain in Comments)*

10. Agency reporting this outbreak:

_____

Contact Person:

NAME: _____
TITLE: _____
PHONE NO: _____
FAX NO: _____
E-MAIL: _____

Date of completion of this form:

___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

☐ **Initial Report**
☐ **Updated Report**
☐ **Final Report**
☐ **Additional data suggests this is not a foodborne outbreak**

Comments: _____

The following codes are to be used to fill out Part 1 (question 9) and Part 2 (question 15).

Contamination Factors:[1]

C1 - Toxic substance part of tissue (e.g., ciguatera)
C2 - Poisonous substance intentionally added (e.g., cyanide or phenolphthalein added to cause illness)
C3 - Poisonous or physical substance accidentally/incidentally added (e.g., sanitizer or cleaning compound)
C4 - Addition of excessive quantities of ingredients that are toxic under these situations (e.g., niacin poisoning in bread)
C5 - Toxic container or pipelines (e.g., galvanized containers with acid food, copper pipe with carbonated beverages)
C6 - Raw product/ingredient contaminated by pathogens from animal or environment (e.g., *Salmonella enteriditis* in egg, Norwalk in shellfish, *E. coli* in sprouts)
C7 - Ingestion of contaminated raw products (e.g., raw shellfish, produce, eggs)
C8 - Obtaining foods from polluted sources (e.g., shellfish)
C9 - Cross-contamination from raw ingredient of animal origin (e.g., raw poultry on the cutting board)
C10 - Bare-handed contact by handler/worker/preparer (e.g., with ready-to-eat food)
C11 - Glove-handed contact by handler/worker/preparer (e.g., with ready-to-eat food)
C12 - Handling by an infected person or carrier of pathogen (e.g., *Staphylococcus*, *Salmonella*, Norwalk agent)
C13 - Inadequate cleaning of processing/preparation equipment/utensils – leads to contamination of vehicle (e.g., cutting boards)
C14 - Storage in contaminated environment – leads to contamination of vehicle (e.g., store room, refrigerator)
C15 - Other source of contamination (*please describe in Comments*)

Proliferation/Amplification Factors:[1]

P1 - Allowing foods to remain at room or warm outdoor temperature for several hours (e.g., during preparation or holding for service)
P2 - Slow cooling (e.g., deep containers or large roasts)
P3 - Inadequate cold-holding temperatures (e.g., refrigerator inadequate/not working, iced holding inadequate)
P4 - Preparing foods a half day or more before serving (e.g., banquet preparation a day in advance)
P5 - Prolonged cold storage for several weeks (e.g., permits slow growth of psychrophilic pathogens)
P6 - Insufficient time and/or temperature during hot holding (e.g., malfunctioning equipment, too large a mass of food)
P7 - Insufficient acidification (e.g., home canned foods)
P8 - Insufficiently low water activity (e.g., smoked/salted fish)
P9 - Inadequate thawing of frozen products (e.g., room thawing)
P10 - Anaerobic packaging/Modified atmosphere (e.g., vacuum packed fish, salad in gas flushed bag)
P11 - Inadequate fermentation (e.g., processed meat, cheese)
P12 - Other situations that promote or allow microbial growth or toxic production (*please describe in Comments*)

Survival Factors:[1]

S1 - Insufficient time and/or temperature during initial cooking/heat processing (e.g., roasted meats/poultry, canned foods, pasteurization)
S2 - Insufficient time and/or temperature during reheating (e.g., sauces, roasts)
S3 - Inadequate acidification (e.g., mayonnaise, tomatoes canned)
S4 - Insufficient thawing, followed by insufficient cooking (e.g., frozen turkey)
S5 - Other process failures that permit the agent to survive (*please describe in Comments*)

Method of Preparation:[2]

M1 - Foods eaten raw or lightly cooked (e.g., hard shell clams, sunny side up eggs)
M2 - Solid masses of potentially hazardous foods (e.g., casseroles, lasagna, stuffing)
M3 - Multiple foods (e.g., smorgasbord, buffet)
M4 - Cook/serve foods (e.g., steak, fish fillet)
M5 - Natural toxicant (e.g., poisonous mushrooms, paralytic shellfish poisoning)
M6 - Roasted meat/poultry (e.g., roast beef, roast turkey)
M7 - Salads prepared with one or more cooked ingredients (e.g., macaroni, potato, tuna)
M8 - Liquid or semi-solid mixtures of potentially hazardous foods (e.g., gravy, chili, sauce)
M9 - Chemical contamination (e.g., heavy metal, pesticide)
M10 - Baked goods (e.g., pies, eclairs)
M11 - Commercially processed foods (e.g., canned fruits and vegetables, ice cream)
M12 - Sandwiches (e.g., hot dog, hamburger, Monte Cristo)
M13 - Beverages (e.g., carbonated and non-carbonated, milk)
M14 - Salads with raw ingredients (e.g., green salad, fruit salad)
M15 - Other, does not fit into above categories *(please describe in Comments)*
M16 - Unknown, vehicle was not identified

[1] Frank L. Bryan, John J. Guzewich, and Ewen C. D. Todd. Surveillance of Foodborne Disease III. Summary and Presentation of Data on Vehicles and Contributory Factors; Their Value and Limitations. Journal of Food Protection, 60; 6:701-714, 1997.
[2] Weingold, S. E., Guzewich JJ, and Fudala JK. Use of foodborne disease data for HACCP risk assessment. Journal of Food Protection, 57; 9:820-830, 1994.

Part 2: Additional Information (Please complete as much as possible)

11. Numbers of:

OUTCOME / SYMPTOM	**Cases** with **Outcome / Symptom**	**Total** cases for whom you have information available
Healthcare Provider Visit		
Hospitalization		
Death		
Vomiting		
Diarrhea		
Bloody stools		
Feverish		
Abdominal cramps		
*		
*		
*		
*		

12. Incubation Period:

(circle appropriate units)

Shortest: _____ (Hours, days)

Longest: _____ (Hours, days)

Median: _____ (Hours, days)

☐ Unknown

13. Duration of Acute Illness Among Those Who Recovered:

(circle appropriate units)

Shortest: _____ (Hours, days)

Longest: _____ (Hours, days)

Median: _____ (Hours, days)

☐ Unknown

* Use the following terms, if appropriate, to describe other common characteristics of cases:

anaphylaxis, arthralgia, bradycardia, bullous skin lesions, bradycardia, cough, coma, diplopia, descending paralysis, flushing, headache, hemolytic uremic syndrome (HUS), hypotension, itching, jaundice, lethargy, myalgia, paresthesia, septicemia, sore throat, tachycardia, thromobocytopenia, temperature reversal, urticaria, wheezing

14. If Cohort Investigation Conducted:

Event-specific Attack Rate = _____ **/** _____ **x 100 =** _____ **%**

 # ill **total # of persons for whom you have illness info.**

15. Implicated Food(s): (Please provide known information.)

Name of Food	**Main Ingredients**	**Contaminated Ingredient**	**Reason(s) Suspected** (see below)	**Method of Preparation** (see list on page 2)
e.g., lasagna	*pasta, sauce, eggs, beef*	*eggs*	*4*	*M1*

☐ Food vehicle could not be determined

Reason Suspected (choose all that apply):

1 - Statistical evidence from epidemiological investigation
2 - Laboratory evidence (e.g., identification of agent in food)
3 - Compelling supportive information
4 - Other data (e.g., same phage type found on farm that supplied eggs)
5 - Specific evidence lacking but prior experience makes this likely source

16. Where was Food Prepared? (Check all that apply)

☐ Restaurant or deli
☐ Day care center
☐ School
☐ Church, temple, etc.
☐ Camp
☐ Caterer
☐ Grocery store
☐ Hospital
☐ Workplace cafeteria
☐ Nursing home
☐ Prison, jail
☐ Private home
☐ Picnic
☐ Fair, festival, other temporary/mobile service
☐ Contaminated food imported into U.S.
☐ Commercial product, served without further preparation
☐ Other (please describe)

_____

17. Where was Food Eaten? (Check all that apply)

☐ Restaurant or deli
☐ Day care center
☐ School
☐ Church, temple, etc.
☐ Camp
☐ Grocery Store
☐ Hospital
☐ Workplace cafeteria
☐ Nursing home
☐ Prison, jail
☐ Private home
☐ Picnic
☐ Fair, festival, or mobile location
☐ Other (please describe)

_____

18. Other Available Info:

☐ Unpublished agency report (please attach)
☐ Epi-Aid
☐ Publication (please reference)

_____

☐ Not available

19. Remarks: Briefly describe important aspects of the outbreak not covered above

(e.g., restaurant closure, product recall, immunoglobulin administration, economic impact, etc.)

_____
_____
_____
_____
_____

State Health Departments: Please FAX this document to Foodborne and Diarrheal Diseases, DBMD, CDC, at (404) 639-2205.

CDC 52.13 REV. 10/2000

GUIDELINES FOR COMPLETING THE FORM "INVESTIGATION OF A FOODBORNE OUTBREAK" Foodborne and Diarrheal Diseases Branch, DBMD, CDC, November 20, 2000

1. Location of Exposure

Provide two-letter postal code of the state, and the full name of the county in which exposure took place. If exposure took place in multiple states or counties (such as with a commercial product), check the box provided and list other states or counties in the Comments section at the bottom of page 1.

2. Dates

Indicate date that first known case patient became ill, and date that the first and last known exposure took place. If available, please send a copy of the epidemic curve along with this report form.

3. Numbers Exposed in Your Jurisdiction

Provide number of laboratory-confirmed cases and number of presumptive cases. If applicable, also provide an estimate of the total number of ill persons if you suspect that this number exceeds the sum of the laboratory-confirmed and presumptive cases.

4. Approximate Percentage of Total Cases in Each Age Group

This item seeks to identify unique patterns of age distribution for the outbreak, as well as to identify age groups most affected. Indicate the approximate percentage of all cases (lab-confirmed and presumptive) in the various age groups listed. Total should equal 100%.

5. Sex

Estimate the percentage of males and females, using all cases (laboratory-confirmed and presumptive combined). Total should equal 100%.

6. Investigation Methods

Check off all boxes that describe the methods used to investigate this outbreak.

7. Implicated Food(s)

List the food item(s) implicated as a result of the investigation. Response to this question should match response to Item 15 on page 3, and should be based on one of the Reasons Suspected given in Item 15.

8. Etiology

a. Identify the bacterium, virus, parasite, or toxin responsible for the outbreak. Please give as much detail as you have about the organism or toxin.

b. Check the box to indicate whether the etiology is confirmed or suspected. "Confirmed" means that the criteria for confirmation of that etiology have been met. (Please visit our Website at: http://www.cdc.gov/ncidod/dbmd/outbreak/guide_fd.htm or see MMWR 2000/ Vol. 49 / ss-1 / Appendix B for confirmation criteria...).

c. If more than one etiology was identified, please describe in the Comments section at the bottom of page 1.

d. Check off all boxes that correspond to the specimen(s) from which the etiologic agent was isolated or identified.

9. Contributing Factors

a. Factors that contribute to the occurrence of outbreaks are classified according to contamination, survival, and proliferation. A factor should be checked only if the investigator has strong evidence that it actually occurred in this outbreak; just because a factor has been cited in similar outbreaks in the past does not mean it was involved in this outbreak. **Contamination factors** relate to how the agent got onto or into the food vehicle. **Proliferation factors** relate to how microbial agents were able to increase in numbers and/or produce toxic products prior to the vehicle being ingested. **Survival factors** refer to processes or steps that should have eliminated or reduced the agent but did not for the reason listed. Explanations and examples of the codes are provided on page 2 of the form. If the choice of "other" is made for any of the factors, please describe in the Comments section at the bottom of page 1.

b. If one or more food workers are implicated as the source of contamination, please indicate what evidence was used to support this conclusion. The choice of "prior experience makes this the likely source" is provided for situations when conclusive laboratory and epidemiologic evidence is absent, but other factors may prompt the investigator to suspect the food worker(s). If a food worker is implicated in the absence of laboratory and/or epidemiologic evidence, please explain in the Comments section at the bottom of page 1.

10. Agency reporting this outbreak

Indicate the agency reporting the outbreak and the relevant information for the person to contact with questions regarding the outbreak investigation. Provide today's date, and indicate whether this is the initial report of the outbreak investigation, or an update to a prior report.

11. Numbers

For each outcome listed, provide the number of patients with the outcome, and the total number of patients for whom you have such outcome information available. If applicable, list other outcomes (and the relevant numbers) in the blank spaces provided. A list of possible outcomes is provided to the right of the table.

12. Incubation Period

Indicate the shortest, longest, and median incubation period, and indicate whether each period is measured in hours or days.

13. Duration of Acute Illness Among Those Who Recovered

Indicate the shortest, longest, and median duration of acute illness among those who recovered. Indicate whether each period is measured in hours or days.

14. If Cohort Investigation Conducted

For cohort investigations only, report the attack rate. The formula is provided to aid in keeping our definition of attack rates consistent across investigations.

15. Implicated Food(s)

Foods implicated in outbreaks may contain multiple ingredients, while often only one of these ingredients is the actual source of the etiologic agent. When possible, identification of an implicated ingredient(s) provides a basis for identifying ingredients that may be involved in other outbreaks. Please list the name of the food, the main ingredients, the contaminated ingredient, and the reason(s) for suspecting that the particular ingredient(s) was contaminated. Indicate method of preparation using list of codes found on page 2 of the form.

16. Where was Food Prepared?

Indicate where food was prepared. Check all applicable boxes.

17. Where was Food Eaten?

Indicate where suspected/implicated food was eaten. Check all applicable boxes.

18. Other Available Information

Indicate what other sources of information are available for this outbreak. References should be cited for published papers.

19. Remarks

Describe other important aspects of the outbreak that may not have been reported elsewhere in the form.

Note: State health departments should fax form to the Foodborne and Diarrheal Diseases Branch, CDC, at 404-639-2205, or mail to: FBO Reporting, Foodborne and Diarrheal Diseases Branch, CDC Mail Stop A-38, 1600 Clifton Road, Atlanta, GA, 30333.

Guidelines for a Public Announcement of Exposure During a Disease Outbreak

It is important to remember that a Public announcement of an outbreak will have several immediate and significant consequences.

1. It will cause concern, both rational and irrational, in the Public.

2. It will cause a possibly catastrophic impact to an establishment specifically named as associated with the outbreak.

3. It will adversely impact any business establishments that are even tangentially linked with the announcement (i.e., other restaurants from the same franchise or with similar sounding names).

4. It may result in a loss of cooperation from some of the principles involved in the outbreak (i.e., restaurant owners, cases who have been contacted by lawyers, etc.).

5. It will increase the flow of inquiries from the Public, thereby absorbing valuable resources that could otherwise be directed at combating the outbreak.

Regardless of those consequences, it is sometimes necessary to make a Public announcement of an outbreak situation. Following are guidelines, adapted from CDC guidelines for announcing a Public Clinic, which can be used to help decide if a Public announcement is appropriate.

All of the following criteria should be met when considering a Public announcement.

1. Does the possibility exist for the Public to have been exposed?

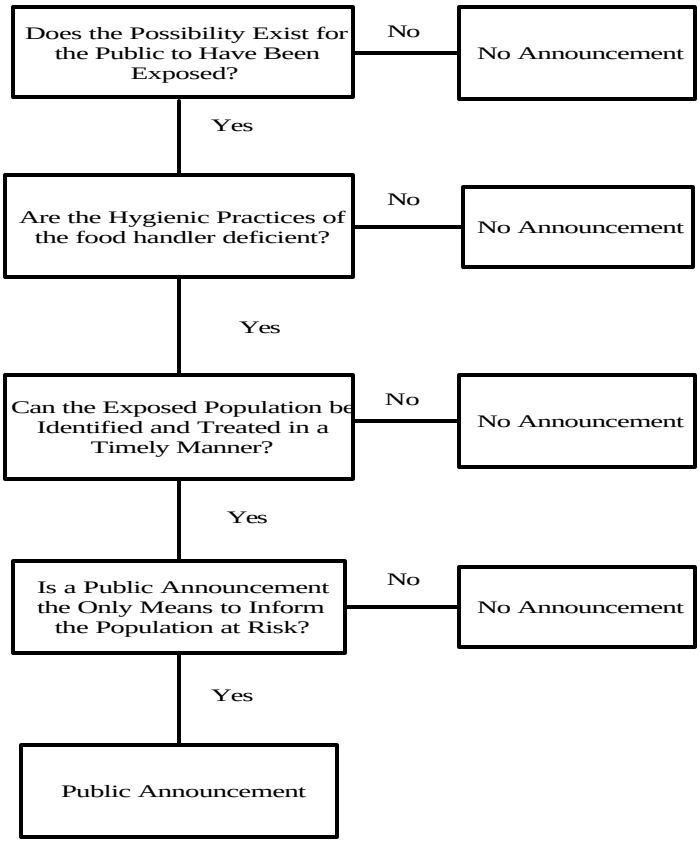
   Did an infectious person handle food, without gloves, that did not receive further cooking before consumption? Examples are:
   - ✓ Lettuce, tomatoes or other garnishes on sandwiches that receive no further heating
   - ✓ Salads, vegetables and fruits at salad bars
   - ✓ Sliced, cooked foods, such as ham or roast, that may be contaminated during slicing or boning procedures.
   - ✓ Cold cuts
   - ✓ Cake icing
   - ✓ Ice that is scooped by hand or with a glass or contaminated scoop
   - ✓ Condiments or garnishes for drinks (olives, cherries, lime wedges etc.)

2. Are the hygienic practices of the food handler known to be deficient, or did the infected person work while having diarrhea?

   A subjective evaluation of the infected person's hygiene may consider such things as:
   - ✓ Appearance of the person's home and living conditions
   - ✓ Personal cleanliness, especially the hands and fingernails
   - ✓ Personal history of handwashing, especially after bowel movements (may be unreliable)
   - ✓ Personal recall of handwashing facilities (color of soap, hot/cold water availability, location of towel dispenser)
   - ✓ Availability of toilet paper, disposable towels, soap, warm water, and unobstructed access to handwashing facilities in the restroom facilities and food preparation area
   - ✓ History of diarrhea while working

3. Can the exposed population be identified and treated in a timely manner?
   - Is there an effective preventive treatment for the illness? (Including education regarding the means of transmission and prevention of spread to secondary cases)?
   - Can such a treatment be administered during the time period for which it would be effective (i.e., within 2 weeks of exposure for IG, etc.)?
   - Are sufficient resources available to administer the prophylactic treatment?

4. Is a public announcement the only means available to inform the population at risk?
   - Is the entire population at risk known?
   - If so, is there another *practical* means to contact them in a timely manner?


Does the Possibility Exist for the Public to Have Been Exposed?
No
No Announcement
Yes
Are the Hygienic Practices of the food handler deficient?
No
No Announcement
Yes
Can the Exposed Population be Identified and Treated in a Timely Manner?
No
No Announcement
Yes
Is a Public Announcement the Only Means to Inform the Population at Risk?
No
No Announcement
Yes
Public Announcement

Etiologic agent	Incubation period	Clinical syndrome	Confirmation
Bacterial			
1. *Bacillus cereus*			
a. Vomiting toxin	1-6 hrs	Vomiting; some patients with diarrhea; fever uncommon	Isolation of organism from stool of two or more ill persons and not from stool of control patients
			OR
			Isolation of 10^5 organisms/g from epidemiologically implicated food, provided specimen is properly handled
b. Diarrheal toxin	6-24 hrs	Diarrhea, abdominal cramps, and vomiting in some patients; fever uncommon	Isolation of organism from stool of two or more ill persons and not from stool of control patients
			OR
			Isolation of 10^5 organisms/g from epidemiologically implicated food, provided specimen is properly handled
2. *Brucella*	Several days to several mos; usually >30 days	Weakness, fever, headache, sweats, chills, arthralgia, weight loss, splenomegaly	Two or more ill persons and isolation of organism in culture of blood or bone marrow; greater than fourfold increase in standard agglutination titer (SAT) over several wks, or single SAT 1:160 in person who has compatible clinical symptoms and history of exposure
3. *Campylobacter jejuni/coli*	2-10 days; usually 2-5 days	Diarrhea (often bloody), abdominal pain, fever	Isolation of organism from clinical specimens from two or more ill persons
			OR
			Isolation of organism from epidemiologically implicated food

4. *Clostridiumbotulinum*	2 hrs-8 days; usually 12-48 hrs	Illness of variable severity; common symptoms are diplopia, blurred vision, and bulbar weakness; paralysis, which is usually descending and bilateral, might progress rapidly	Detection of botulinal toxin in serum, stool, gastric contents, or implicated food
			OR
			Isolation or organism from stool or intestine
5. *Clostridium perfringens*	6-24 hrs	Diarrhea, abdominal cramps; vomiting and fever uncommon	Isolation of 10^5 organisms/g from stool of two or more ill persons, provided specimen is properly handled.
			OR
			Demonstration of enterotoxin in the stool of two or more ill persons
			OR
			Isolation of 10^5 organisms/g from epidemiologically implicated food, provided specimen is properly handled
6. *Escherichia coli*			
a. Enterohemorrhagic (*E. coli* O157:H7 and others)	1-10 days; usually 3-4 days	Diarrhea (often bloody), abdominal cramps (often severe), little or no fever	Isolation of *E. coli* O157:H7 or other Shiga-like toxin-producing *E. coli* from clinical specimen from two or more ill persons
			OR
			Isolation of *E. coli* O157:H7 or other Shiga-like toxin-producing *E. coli* from epidemiologically implicated food

b. Enterotoxigenic (ETEC)	6-48 hrs	Diarrhea, abdominal cramps, nausea; vomiting and fever less common	Isolation of organism of same serotype, demonstrated to produce heat-stable (ST) and/or heat-labile (LT) enterotoxin, from stool of two or more ill persons
c. Enteropathogenic (EPEC)	Variable	Diarrhea, fever, abdominal cramps	Isolation of organism of same enteropathogenic serotype from stool of two or more ill persons
d. Enteroinvasive (EIEC)	Variable	Diarrhea (might be bloody), fever, abdominal cramps	Isolation of same enteroinvasive serotype from stool of two or more ill persons
7. *Listeria monocytogenes*			
a. Invasive disease	2-6 wks	Meningitis, neonatal sepsis, fever	Isolation of organism from normally sterile site
b. Diarrheal disease	Unknown	Diarrhea, abdominal cramps, fever	Isolation of organism of same serotype from stool of two or more ill persons exposed to food that is epidemiologically implicated or from which organism of same serotype has been isolated
8. Nontyphoidal *Salmonella*	6 hrs-10 days; usually 6-48 hrs	Diarrhea, often with fever and abdominal cramps	Isolation of organism of same serotype from clinical specimens from two or more ill persons
			OR
			Isolation of organism from epidemiologically implicated food
9. *Salmonella* Typhi	3-60 days; usually 7-14 days	Fever, anorexia, malaise, headache, and myalgia; sometimes diarrhea or constipation	Isolation of organism from clinical specimens from two or more ill persons
			OR
			Isolation of organism from epidemiologically implicated food

10. *Shigella* spp.	12 hrs-6 days; usually 2-4 days	Diarrhea (often bloody), often accompanied by fever and abdominal cramps	Isolation of organism of same serotype from clinical specimens from two or more ill persons
			OR
			Isolation of organism from epidemiologically implicated food
11. *Staphylococcus aureus*	30 min-8 hrs; usually 2-4 hrs	Vomiting, diarrhea	Isolation of organism of same phage type from stool or vomitus of two or more ill persons
			OR
			Detection of enterotoxin in epidemiologically implicated food
			OR
			Isolation of 10^5 organisms/g from epidemiologically implicated food, provided specimen is properly handled
12. *Streptococcus*, group A	1-4 days	Fever, pharyngitis, scarlet fever, upper respiratory infection	Isolation of organism of same M- or T-type from throats of two or more ill persons
			OR
			Isolation of organism of same M- or T-type from epidemiologically implicated food

13. *Vibrio cholerae*			
a. O1 or O139	1-5 days	Watery diarrhea, often accompanied by vomiting	Isolation of toxigenic organism from stool or vomitus of two or more ill persons
			OR
			Significant rise in vibriocidal, bacterial-agglutinating, or antitoxin antibodies in acute- and early convalescent-phase sera among persons not recently immunized
			OR
			Isolation of toxigenic organism from epidemiologically implicated food
b. non-O1 and non-O139	1-5 days	Watery diarrhea	Isolation of organism of same serotype from stool of two or more ill persons
14. *Vibrio parahaemolyticus*	4-30 hrs	Diarrhea	Isolation of Kanagawa-positive organism from stool of two or more ill persons
		OR	
			Isolation of 10^5 Kanagawa-positive organisms/g from epidemiologically implicated food, provided specimen is properly handled
15. *Yersinia enterocolitica*	1-10 days; usually 4-6 days	Diarrhea, abdominal pain (often severe)	Isolation of organism from clinical specimen from two or more ill persons
		OR	
			Isolation of pathogenic strain of organism from epidemiologically implicated food

Chemical			
1. Marine toxins			
a. Ciguatoxin	1-48 hrs; usually 2-8 hrs	Usually gastrointestinal symptoms followed by neurologic symptoms(including paresthesia of lips, tongue, throat, or extremities) and reversal of hot and cold sensation	Demonstration of ciguatoxin in epidemiologically implicated fish
			OR
			Clinical syndrome among persons who have eaten a type of fish previously associated with ciguatera fish poisoning (e.g., snapper, grouper, or barracuda)
b. Scombroid toxin (histamine)	1 min-3 hrs; usually <1 hr	Flushing, dizziness, burning of mouth and throat, headache, gastrointestinal symptoms, urticaria, and generalized pruritis	Demonstration of histamine in epidemiologically implicated fish
			OR
			Clinical syndrome among persons who have eaten a type of fish previously associated with histamine fish poisoning (e.g., mahi-mahi or fish of order Scomboidei)
c. Paralytic or neurotoxic shellfish	30 min-3 hrs	Paresthesia of lips, mouth or face, and extremities; intestinal symptoms or weakness, including respiratory difficulty	Detection of toxin in epidemiologically implicated food
			OR
			Detection of large numbers of shellfish-poisoning-associated species of dinoflagellates in water from which epidemiologically implicated mollusks are gathered

d. Puffer fish, tetrodotoxin	10 min-3 hrs; usually 10-45 min	Paresthesia of lips, tongue, face, or extremities, often following numbness; loss of proprioception or floating sensations	Demonstration of tetrodotoxin in epidemiologically implicated fish
			OR
			Clinical syndrome among persons who have eaten puffer fish
2. Heavy metals	5 min-8 hrs; usually <1 hr	Vomiting, often metallic taste	Demonstration of high concentration of metal in epidemiologically implicated food
• **Antimony** • **Cadmium** • **Copper** • **Iron** • **Tin** • **Zinc**			
3. Monosodium glutamate (MSG)	3 min-2 hrs; usually <1 hr	Burning sensation in chest, neck, abdomen, or extremities; sensation of lightness and pressure over face or heavy feeling in chest	Clinical syndrome among persons who have eaten food containing MSG (e.g., usually 1.5 g MSG)

4. Mushroom toxins			
a. Shorter-acting toxins	2 hrs	Usually vomiting and diarrhea, other symptoms differ with toxin	Clinical syndrome among persons who have eaten mushroom identified as toxic type
• **Muscimol** • **Muscarine** • **Psilocybin** • ***Coprinus artrementaris*** • **Ibotenic acid**		• Confusion, visual disturbance • Salivation, diaphoresis • Hallucinations • Disulfiram-like reaction • Confusion, visual disturbance	OR
			Demonstration of toxin in epidemiologically implicated mushroom or food containing mushroom
b. Longer-acting toxins (e.g., *Amanita*spp.)	6-24 hrs	Diarrhea and abdominal cramps for 24 hrs followed by hepatic and renal failure	Clinical syndrome among persons who have eaten mushroom identified as toxic type
			OR
			Demonstration of toxin in epidemiologically implicated mushroom or food containing mushrooms
Parasitic			
1. *Cryptosporidium parvum*	2-28 days; median: 7 days	Diarrhea, nausea, vomiting; fever	Demonstration of organism or antigen in stool or in small-bowel biopsy of two or more ill persons
			OR
			Demonstration of toxin in epidemiologically implicated food

2. *Cyclospora cayetanensus*	1-11 days; median: 7 days	Fatigue, protracted diarrhea, often relapsing	Demonstration of organism in stool of two or more ill persons
3. *Giardia lamblia*	3-25 days; median: 7 days	Diarrhea, gas, cramps, nausea, fatigue	Two or more ill persons and detection of antigen in stool or demonstration of organism in stool, duodenal contents, or small-bowel biopsy specimen
4. *Trichinella*spp.	1-2 days for intestinal phase; 2-4 wks for systemic phase	Fever, myalgia, periorbital edema, high eosinophil count	Two or more ill persons and positive serologic test or demonstration of larvae in muscle biopsy
			OR
			Demonstration of larvae in epidemiologically implicated meat
Viral			
1. Hepatitis A	15-50 days; median: 28 days	Jaundice, dark urine, fatigue, anorexia, nausea	Detection of immunoglobulin M anti-hepatitis A virus in serum from two or more persons who consumed epidemiologically implicated food

2. Norwalk family of viruses, small round-structured viruses (SRSV)	15-77 hrs; usually 24-48 hrs	Vomiting, cramps, diarrhea, headache	More than fourfold rise in antibody titer to Norwalk virus or Norwalk-like virus in acute and convalescent sera in most serum pairs
			OR
			Visualization of small, round-structured viruses that react with patient's convalescent sera but not acute sera — by immune-electron microsopy (assays based on molecular diagnostics [e. g., polymerase-chain reaction, probes, or assays for antigen and antibodies from expressed antigen] are available in reference laboratories)
3. Astrovirus, calicivirus, others	15-77 hrs; usually 24-48 hrs	Vomiting, cramps, diarrhea, headache	Visualization of small, round-structured viruses that react with patient's convalescent sera but not acute sera — by immune-electron microsopy (assays based on molecular diagnostics [e. g., polymerase-chain reaction, probes, or assays for antigen and antibodies from expressed antigen] are available in reference laboratories)

MULTISTATE FOODBORNE OUTBREAK INVESTIGATIONS

GUIDELINES FOR IMPROVING COORDINATION AND COMMUNICATION

National Food Safety System Project
Outbreak Coordination and Investigation Workgroup
February 2001

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Mission Statement

To improve coordination, cooperation and communication among local, state and federal agencies with respect to multistate foodborne outbreak investigations.

Goals

- To develop a model for coordinating, cooperating, and communicating before, during, and after a multistate foodborne outbreak investigation.

- To inform the public, industry, and trade groups about multistate outbreak coordination process and encourage their active cooperation.

Background

In response to the growing concerns over foodborne illnesses and the coordination of food safety activities at all levels of government, a meeting of governmental agencies was convened in Kansas City in 1998. The meeting was attended by epidemiologists, laboratory scientists, environmental health specialists, food regulators and agriculture representatives from local, state and federal agencies. The purpose was to develop ways to integrate overlapping responsibilities and mutual goals for food safety in the United States. From that meeting, six working groups were created to address problem areas identified by the meeting participants as part of the National Food Safety System (NFSS) project. The Outbreak Coordination and Investigation Workgroup, one of the six, was charged with improving coordination among agencies with regard to multistate outbreaks of foodborne illness and developing guidelines for the coordination of investigations of these outbreaks. These guidelines, developed over 2 years, represent the efforts of representatives from the U.S. Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA); the U.S. Environmental Protection Agency (EPA); the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), and state and local epidemiologists, laboratory scientists, and agriculture officials.

Audience

Local, state and federal agencies, including public health, epidemiology, environmental, laboratory, and agriculture representatives, industry, professional organizations, and the public.

Introduction

In recent years, the reported incidence of foodborne-disease outbreaks that extend beyond state borders has increased. This is the result of many factors, including wider food distribution networks, contamination prior to the point of service, and better surveillance methods. Investigations of these large, multistate outbreaks often involve numerous agencies with differences in approaches, missions and regulatory jurisdictions that need to be recognized and understood by participants in the investigations. Historically, governmental agencies have worked independently within their scope of responsibility; many local, state and federal agencies, therefore, are not well informed regarding the coordination needed among the various agencies during multistate foodborne outbreaks. To address these new situations, communication and coordination within and among local, state and federal government agencies need to be improved, and new mechanisms and processes need to be developed to achieve this improvement.

Identifying and investigating a multistate foodborne outbreak, conducting traceback and source investigations, developing and implementing control measures, and taking steps to prevent recurrence are all activities that require close coordination between the many different players. Local, state, and federal agencies have recognized the need for improving coordination efforts in this process.

These guidelines provide a framework for local, state and federal agencies to effectively respond to multistate foodborne outbreaks. The scope of this document is intended to cover the following foodborne hazards: microbial, microbial toxin, toxic chemical, pesticides, and foreign objects. The concepts and principles of this document can work equally well for recognizing and responding to public health emergencies associated with any of these hazards.

This document currently covers surveillance, illness investigation and product investigation. Other important topics related to multistate outbreaks are being developed and are listed in the table of contents.

Chapter 1. RECOGNITION
Detecting Multistate Foodborne Outbreaks

Key Points:

- **The recent increase of widely dispersed foodborne outbreaks requires improved surveillance and response systems.**
- **Early detection of potential multistate outbreaks, using distinguishing characteristics or indicators, can lead to earlier notification, intervention, and prevention of illnesses.**
- **Enhancing current surveillance systems to identify multistate outbreaks as early as possible will maximize control and prevention efforts.**

The increasing numbers of reported multistate outbreaks of foodborne illness, many detected by improved surveillance and laboratory techniques such as FoodNet and PulseNet, highlight the fact that early and frequent communication among investigating agencies is critical in controlling outbreaks and preventing additional illnesses. Although preliminary investigations of foodborne illness may not determine whether the outbreak is truly multistate, several potential indicators may alert investigators to a heightened awareness of such outbreaks and can result in earlier detection. These potential indicators are listed in Table 1.

Table 1. Indicators that may lead to early detection of multistate foodborne outbreaks

Indicator	Feature of Widely Disseminated or Multistate Foodborne Outbreak
Geographic area affected	Multiple cases and/or clusters in several counties, states, or even countries occurring over a similar time period
Point of contamination	Early in the production/distribution chain
Implicated food	Widely distributed food (nationally or internationally)
Pathogen	Emerging or rarely encountered in the affected geographic areas
Point of sale or service	Tourist facility, airport, convention center, restaurant or grocery chain

A foodborne outbreak investigation can begin only after cases are detected and reported through disease surveillance. All states require certain diseases to be reported to local or state health officials. Disease reports are usually transmitted from health care providers and laboratories to local, county, or state health departments. Information is then passed from state health departments to federal agencies. Prompt submission of information surrounding epidemiologic investigations, analysis and interpretation of data is critical in detecting widely dispersed outbreaks.

In addition to epidemiologic or laboratory surveillance, a parallel environmental health surveillance system monitors the safety of food products by conducting facility inspections, sampling foods, and monitoring consumer complaints.

Table 2 lists specific activities that can improve and hasten the detection of multistate foodborne-disease outbreaks.

Table 2. Activities that can improve the detection of multistate foodborne outbreaks

- Timely and complete reporting of foodborne disease cases/clusters.
- Collection and analysis of specimens from infected persons and foods for culturing and other studies to identify the etiologic agent of foodborne outbreaks.
- Referral of specimens to local, state or federal public health laboratories for serotyping and molecular fingerprinting.
- Serotyping and molecular epidemiology studies of isolated pathogens (e.g., PFGE, viral sequencing) from human and food samples.
- Real-time analysis of surveillance data at local, state, and national levels to detect geographically and temporally related illness clusters (e.g., PHLIS, SODA, and PulseNet).
- Sharing of information on pathogen identification.
- Rapid hypothesis-generating investigation(s).
- Prompt completion of local and multistate case-control and/or cohort studies to determine if there is a common exposure.
- Early alerts to surrounding county, city, and state agencies (epidemiology, environmental health, and laboratories).
- Early involvement and communication with experienced personnel.

Expanded surveillance requires additional training and resources at local, state and federal agencies. Training should be ongoing and should emphasize interagency cooperation and coordination. Resources at the local and state levels should include adequate staffing for conducting epidemiologic, environmental, and laboratory surveillance and data analysis. To identify potential multistate outbreaks as early as possible and prevent further illness, it is imperative to communicate information to other involved agencies when the outbreak is detected and the investigation is ongoing rather than waiting until it has been completed. States are encouraged to review surveillance data from counties to determine those jurisdictions that may be underreporting or not reporting at all.

Chapter 2. OUTBREAK RESPONSE
Section A. Foodborne Illness/Outbreak Investigation

Key Points:

- **Communicate early, often, and accurately.**
- **Foster regular, horizontal and vertical communications among local, state and federal agencies.**
- **Understand roles/responsibilities of agencies responsible for food safety activities.**
- **Develop and use standard procedures to allow interagency consistency.**
- **Identify agency/department leaders and points of contact early in outbreaks.**
- **Develop and maintain contact lists.**

Many references are available on how to conduct a foodborne outbreak investigation. The purpose of this document is to present a model for coordinating, cooperating, and communicating before, during, and after a multistate foodborne outbreak investigation and to inform the public, industry, and trade groups about the multistate outbreak coordination process and encourage their active cooperation.

This chapter will focus on four factors identified at the local, state and federal levels as critical to a successful multistate investigation: 1) communication (including early alerts, emergency contact lists and conference calls), 2) clearly defined roles and responsibilities, 3) standardized procedures, and 4) resources.

COMMUNICATION

Communication is one of the most important factors in the coordination of multistate foodborne outbreak investigations. Table 3 provides a list of suggestions for improving communication and cooperation at all levels during a multistate foodborne outbreak.

Table 3. Suggestions for improving communication and coordination efforts during multistate foodborne outbreak investigations

- Develop communication protocols or standard operating procedures (SOPs) for the following groups:
  - Health care professionals and community sources
  - Consumers
  - Media
  - Industry

- Develop emergency contact lists and identify the contact for your agency (Appendix A, B, C, D). Update as needed for each outbreak investigation. Distribute contact lists to other agencies.

- Develop standardized templates for sharing information with other agencies (Appendix E).

- Include questions from a nationally standardized questionnaire for foodborne outbreak investigations. This may be useful if a multistate case control study is conducted.

- Complete the CDC Outbreak Reporting form (Reference section) as soon as possible after the investigation has begun and/or the investigation has been completed and forward to the appropriate state agency (to be forwarded to CDC) or send directly to CDC.

- Develop a resource notebook with specific examples of public health information for communicating with the public and other health professionals during a foodborne outbreak. FDA, CDC, and FSIS have examples of some of these available on their websites.

- Develop a list of data points that should be completed in each investigation, including epidemiologic, environmental and laboratory elements (Appendix F).

- Develop a laboratory reference sheet that includes the following information for common foodborne pathogens: food sample and human specimen collection protocols, pathogen-specific standard laboratory tests and analyses, equipment lists, and storage and shipping needs for specimens and isolates.

- Foster working relationships and host meetings with other agencies, the media, consumer groups and industry not related to specific outbreak investigations.

- Participate in multistate, multi-agency conference calls during an outbreak investigation and provide training for staff in conference call etiquette.

Early Alerts

In addition to identifying multistate outbreaks as early as possible to prevent further illness, investigators must communicate information to other agencies as soon as possible rather than waiting until the investigation has been completed. Tables 4 and 5 provide guidelines for determining when to notify other health and regulatory agencies. Each agency may need to modify this guide according to its particular requirements and for different types of outbreaks. These tables may be used in conjunction with Appendices J and K to determine which federal agency should be notified.

Table 4. Guidelines for notification of other agencies

Stage	Stage Description (Outbreak Detection)	Agency Level	Agencies to be notified (Regulatory agency depends upon nature of suspected vehicle)
1	▪ Local cluster(s) of suspected foodborne/ waterborne illness detected	Local	▪ Affected and surrounding county, city health departments (epi, EH, lab) ▪ State health department
2	▪ Clusters detected in multiple counties ▪ An increase in sporadic cases statewide ▪ Matching serotype, subtype, PFGE pattern	Local/ state	▪ Surrounding state health departments (epi, EH, lab) ▪ CDC ▪ Federal regulatory agency district offices (FSIS, FDA, EPA)
3	▪ Clusters detected in multiple states ▪ Food product or water suspected or implicated ▪ Increase in sporadic cases (regionally or nationally) with matching serotype, subtype, PFGE	Local/ state/ federal	▪ CDC ▪ State and local health departments ▪ FSIS, FDA, EPA district and headquarters offices ▪ Foreign countries will be notified by federal agencies as appropriate

An Early Alert Fax/Email Template can be used by any agency to notify surrounding counties, state epidemiology and food safety offices, and FSIS or FDA district offices when an outbreak is detected. Appendix E is an example of such a template; agencies may use this form or develop their own. In addition, CDC's recently developed EPI-X is an early alert network for health agencies to provide electronic notification to each other and CDC.

Table 5. Early alert situations

CDC and the appropriate Federal Regulatory Agencies (FSIS, FDA, or EPA) should be notified when any of the following occur:

- An unusual or virulent pathogen or a chemical or pesticide is suspected in an outbreak or detected in a product.
- A pathogen, chemical, or pesticide is found in a food that may be distributed in interstate commerce.
- An outbreak occurs on an international or interstate airplane, bus, train, or vessel.
- Intentional product contamination is suspected.
- The suspected food item is:
  - Imported
  - Previously implicated in multistate outbreaks
  - Prepackaged
  - Transported across state lines
  - Regulated by FDA (Appendices J & K)
  - Manufactured in an FSIS-regulated facility (Appendices J & K)

Emergency Contacts

Emergency contacts should be identified at local, state and federal levels before a foodborne outbreak occurs. Appendix A provides a list of federal agency emergency headquarters contacts. For both FSIS and FDA, early alerts should be sent to the local FSIS and FDA district offices (Appendices B & C), who will then notify FSIS and FDA headquarters. A template has been included in Appendix D for agencies to identify local and state contacts for notification during a foodborne outbreak.

Multistate, multi-agency conference calls

During the early phases of a multistate foodborne outbreak, efforts will focus upon the epidemiologic phase of the investigation in each state. In this phase, CDC may convene regularly scheduled conference calls between epidemiologists (local, state, federal) in the affected states to provide updates on the progress of the investigations in each state and to provide epidemiologic and laboratory guidance and support. If an outbreak is thought to be associated with an interstate product, FSIS and/or FDA and EPA (if appropriate) should also be included in the early phases of the investigation.

Regulatory agencies should be included in these conference calls so that they can understand the methods, findings and conclusions and so that the implicated product(s) can be removed from the

market as rapidly as possible to prevent additional illnesses. Tables 6 and 7 outline the essential items that should be covered in early-phase and later-phase conference calls.

Table 6: Conference calls in the early phase of a multistate foodborne outbreak investigation

- Calls may be initiated by a local, state or federal health agency, usually hosted by CDC or one of the states.
- Epidemiologic investigations discussed.
- Epidemiologic and laboratory guidance provided.
- Multistate case control studies may be discussed and planned.
- Information exchanged on methods, findings and conclusions.
- Discussion and coordination of media issues.

Additionally, CDC may ask two or more of the affected states and/or local health departments to conduct a standardized epidemiologic study to identify the item responsible for the outbreak. If a food item is determined to be associated with the outbreaks, the focus of the investigation shifts to the product investigation phase, which may include food product sampling and analysis, tracebacks, facility inspections, food preparation reviews, and farm/source investigations.

Table 7. Conference calls in the later phase of a multistate foodborne outbreak investigation

- Multistate conference calls may be initiated by a local, state or federal regulatory agency, usually hosted by FDA, FSIS or EPA.
- Facility inspections, product sampling and analysis, food preparation reviews, traceback and source investigations discussed.
- Environmental and food laboratory guidance provided.
- Exchange of methods, findings and conclusions, regulatory actions.
- Discussion and coordination of media issues.

In this phase of the investigation, the appropriate regulatory agency (FDA/FSIS/EPA) may convene regularly scheduled conference calls between food regulators in the affected states to plan the approach to the environmental investigation, share the current status of the investigations, and provide environmental/regulatory guidance and support. CDC and state and

local epidemiology staff should be included in these conference calls to provide updates on the ongoing epidemiologic investigations. Multi-state conference calls are an important tool for improving coordination and communication among the different agencies. Appendix G provides guidelines for conference call etiquette. It is recommended that staff members participating in these calls receive training in conference call etiquette.

ROLES AND RESPONSIBILITIES

As more multistate foodborne outbreaks are identified, it is critical that investigators understand their own role as well as the roles that other agencies have in these investigations. Each federal agency has a different mission and authorizing legislation, resulting in different approaches before, during, and after an investigation. Appendix H lists the responsibilities of the federal agencies involved in foodborne outbreak investigations. A similar list should be developed within each state/locality describing state and local agency roles and responsibilities. Appendices I (a) and (b) outline the involvement by agency level during the stages of a multistate foodborne outbreak and the different areas of investigation: epidemiology, laboratory and environmental.

Individuals and agencies participating in these investigations should be knowledgeable of the functions of all the agencies involved (Table 8).

Table 8. Defining roles and responsibilities

- Know the lead contact person in each agency involved in the investigation.
- Understand the roles and responsibilities of each agency responsible for food safety activities.
- Understand the laws governing release of confidential information in your state. Be aware that there are different laws governing commercial and medical confidential information, which may prevent the sharing of some information between agencies and limit public disclosure.

Federal Regulatory Agencies and Jurisdictions

Local, state and federal agencies should be able to determine which federal regulatory agency has jurisdiction over a suspected or implicated food product. Appendices J & K provide guidelines for determining which agency to notify when a food item is suspected or implicated. Appendix H also outlines the federal agency jurisdictions.

If bottled water or ice is suspected or implicated in a multistate outbreak, FDA and EPA should both be notified. FDA has regulatory jurisdiction over the packaged product (if it moved in interstate commerce), and EPA has jurisdiction over the water source. In cases of a multistate waterborne outbreak associated with drinking (tap) water or recreational water, EPA should be

notified.

For any food (including animal feed) or water product that has been contaminated with a chemical or pesticide or if contaminated water is suspected, EPA and FDA or FSIS should be notified. EPA should be provided with the pesticide product that is involved and the EPA registration number and/or the exact product name (if known). If water is used in the processing or manufacture of a food product implicated in a multi-state foodborne outbreak, EPA and either FSIS or FDA should be notified.

If product is available, samples should be taken according to prescribed procedures. FDA, FSIS, and EPA (depending upon the product) should be consulted about how the product should be sampled, how much product is needed, and how and where it should be shipped.

STANDARDIZED PROCEDURES

Each agency should approach foodborne outbreak investigations in a standardized manner. A standardized approach is critical in responding in a timely manner to multistate outbreaks and can save time and resources. National surveillance systems must receive information in a standardized format in order to be incorporated into a large database. In addition, CDC, in cooperation with the states, has developed a nationally standardized foodborne outbreak questionnaire, available on the CDC web site. Local and state agencies may conduct an investigation, only to discover later that the outbreak is part of a multistate outbreak. Large multistate case-control studies are time and resource intensive, and the need to re-interview case-patients and controls can be obviated by the use of standardized questionnaires.

Basic Operating Procedures

Any agency responsible for responding to foodborne outbreaks should develop a procedure manual for responding to such outbreaks. A suggested table of contents for a basic operating procedures manual for multistate foodborne outbreak coordination is provided in Appendix L. In addition, several health departments have developed manuals, and some of these are listed in the Reference section.

RESOURCES

For an outbreak investigation to be successful, agencies need adequate resources in epidemiology, laboratory and environmental health. CDC has developed a Core Capacity document (unpublished) that outlines the resources necessary to conduct foodborne surveillance and investigations. This document has been distributed to all state health departments. Investigatory agencies at all levels should openly discuss their resources and priorities throughout the investigation to minimize delays. Agencies may be able to help others with procedures such as sample collections, laboratory tests, or conducting interviews.

Chapter 2. OUTBREAK RESPONSE
Section B. Product Investigation

Key Points:

- **Product investigations include food preparation reviews, traceback investigations, and inspections.**
- **A traceback investigation is the method used to determine the source and scope of the product/processes associated with the outbreak and document the distribution and production chain of the product that has been implicated in a foodborne illness or outbreak.**
- **A source or product investigation may be conducted to determine possible points of contamination.**
- **Tracebacks can be conducted for epidemiologic and/or regulatory purposes. Federal regulatory agencies coordinate multistate tracebacks.**
- **Federal agencies will review results using criteria from three areas (epidemiologic, environmental and laboratory) before initiating a traceback for regulatory purposes.**
- **The cooperation of industries should be fostered before outbreaks occur to facilitate tracebacks and source/farm investigations when they are needed.**

A product investigation begins when a specific food is suspected or implicated in a foodborne illness outbreak. Product investigations can involve facility inspections, a food preparation review, and environmental and traceback investigations. Local and state environmental health investigators and inspectors from regulatory agencies initially conduct product investigations. If a product falls under federal jurisdiction, FDA or FSIS will coordinate inspections with the local and state investigators.

A food can be implicated or associated with a foodborne outbreak through one or more of the following methods: epidemiologic or statistical, laboratory and/or a thorough food preparation review (Table 9).

Table 9. Methods used to implicate or associate a product with a foodborne outbreak

- An epidemiologic investigation shows an association (not necessarily statistical) between a food and illness.
- A laboratory analysis of the implicated food sample tests for the same pathogen, toxin, or contaminant (same serotype or PFGE pattern) that was detected in clinical specimens.
- A food preparation review identifies a possible vehicle(s) and contributing factors that could have resulted in the illness under investigation.

Traceback investigations

A traceback investigation is used to determine the source of the product associated with the outbreak and document the distribution and production chain of the product that has been implicated in a foodborne illness or outbreak (Table 10). A subsequent source or product investigation may be conducted to determine possible points of contamination. A source may be determined to be a consumer, retailer, restaurant or food service, water source, farm, estuary, harvester, transporter, producer, processor or manufacturer.

Table 10. Purposes of traceback investigations

- Identify the source and distribution of foods in order to alert the public and remove contaminated product from the marketplace.
- Distinguish between two or more vehicles.
- Compare distribution of illnesses and distribution of product in order to strengthen an epidemiologic association. This is referred to as an "epi" traceback.
- Determine potential route or source of contamination by evaluating common distribution sites, processors or growers.

An increase in the recognition and investigation of food products associated with multistate foodborne outbreaks has led to a greater need for traceback investigations. Participants at all levels of outbreak investigations have expressed frequent concern about the inadequate epidemiologic, environmental or laboratory evidence to support initiation of a traceback investigation. Other difficulties associated with these investigations include poorly defined roles and responsibilities, insufficient resources available to conduct the investigations, inadequate record keeping about product distribution, and legal and organizational barriers to sharing of data

and information. Traceback investigations can require extensive resources and can result in irreparable damage to food firms. Therefore, it is critical that each piece of the investigation (epidemiologic, laboratory, and environmental) is thorough, complete, and accurate.

A regulatory traceback investigation of a product can be initiated when epidemiologic, environmental or laboratory evidence implicates a food product and other contributing causes (e.g., cross-contamination, ill food workers at the point of service) are not likely (Table 11). If a food is implicated in a multistate outbreak, the responsible federal regulatory agency will need to confirm the epidemiologic association before initiating a multistate traceback investigation or regulatory response.

Table 11. Factors to be considered before initiating a traceback investigation

- Adequate epidemiologic, laboratory and environmental evidence
- Disease severity
- Risk of ongoing exposure
- Reliable exposure information (date and place)
- Availability of shipping records
- Availability of resources for conducting traceback investigations

Before initiating a multistate traceback investigation, the federal regulatory agencies may request a written summary of the results of the epidemiologic, environmental and laboratory investigations from the agencies that conducted the investigations (Table 12). The summaries should include the available information that has been listed in the Checklist for Communicating Findings (Appendix F). The federal agencies may also request that CDC and/or other epidemiologists evaluate the epidemiologic data.

Table 12. Information requested and reviewed before initiating a multistate traceback investigation

- A written epidemiologic summary to address the items specified in Appendix F (if available).
- Environmental or inspection reports, including a complete food preparation review, for local, state and/or federal investigators to determine if contamination at the point of service is a probable cause of the outbreak.
- Laboratory confirmation, if possible, of the agent(s) isolated from patients and/or the food product.
- Copies of invoices and other distribution information collected by local and state investigators.

Coordination of multistate tracebacks

During the early phases of an outbreak investigation, an "epidemiologic" traceback is sometimes conducted. Epidemiologists may use product distribution data as a tool to test hypotheses, distinguish between multiple vehicles, and strengthen an epidemiologic association. A traceback that begins for epidemiologic reasons can quickly develop into a regulatory or "product" investigation as appropriate evidence is obtained.

Multistate and interstate traceback investigations will be coordinated at the federal level by the agency (FSIS or FDA) having regulatory authority for the food product. If product distribution records are being requested in the course of an epidemiologic investigation, the local district offices of FDA or FSIS should be notified. This early contact is critical for coordinating and conducting tracebacks. The local, state or federal agency requesting the traceback data should consult with the federal regulatory agency (FDA or FSIS) in determining what information will be needed if the traceback becomes a regulatory or product traceback. This will save time and duplication of effort if a traceback is initiated later by the federal agencies. Federal agencies may need to take regulatory action in some instances, and documentation of the events and data are required.

When the local district offices (FSIS or FDA) are notified of an outbreak or a request for traceback investigation, they will immediately notify their contacts in headquarters. The Epidemiology Branch of FSIS (USDA) and the Division of Emergency and Investigational Operations, DEIO (FDA) will be the federal agency contact points for all food-related emergencies and traceback investigations. The contact information for these offices is given in Appendix A. For both FDA- and FSIS-initiated tracebacks, the investigation will be conducted by the local District offices (Appendices B & C). Federal headquarters offices will coordinate the investigations with the district offices and other agencies.

As the number of multistate outbreak investigations increases, the number of traceback investigations will also increase, requiring additional resources at all levels of government. The methods described in the FDA "Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations, July 1998" should be used in all tracebacks of fresh fruits and vegetables. A revised version of this document (available in the spring of 2001) will include additional guidance for other commodities. These methods may also be applicable to other commodities that do not have labeling or packaging.

Sharing traceback information

One of the most difficult obstacles in the coordination and communication of traceback investigations is sharing of information. According to current federal law, FDA and FSIS must treat as "commercial confidential" traceback information (customer and distribution information), whether collected for epidemiologic or regulatory reasons. Therefore much of this information cannot be shared with other agencies unless it can be protected from being released publicly. This is equivalent to patient health information that is also protected by law. Releasing commercial confidential information can unfairly harm a company and an industry. Regulatory

agencies can be sued for destroying a company's reputation, and federal regulators can suffer severe criminal penalties for releasing this information.

For USDA-regulated products, a code is printed on the product label. If this code is available, the product can easily be traced to the manufacturer and a recall can be initiated. Information regarding recalled USDA-regulated product (brand name, manufacturer, lot numbers) is public information. However, if a pathogen is detected in a product in a meat processing facility (these are monitored and tested by USDA) and that product has never reached the market (held at a plant), the public has never been at risk from the product. That information is not public and cannot be released.

For FDA-regulated products that are packaged, the name of a distributor or manufacturer may appear on the label; the product can easily be traced back to the manufacturer and a recall can be initiated. Information , such as labeling, lot numbers, and brand name, regarding a recalled FDA-regulated product is public information. This does not include the list of customers who received the product that is under recall. The list of customers, or consignees, is confidential and is protected from public release by law. The list of states that may have received the product is usually available to the public. For most fresh produce, packaging and labeling are rarely available. Tracebacks are the only way to determine the potential sources of the product (not necessarily the source of the contamination). If a source or sources of the product can be determined through a traceback investigation, an investigation is conducted at those firms or farms.

A recall and/or a traceforward is rarely undertaken for fresh produce for several reasons: 1) the product is not readily identifiable by consumers (no packaging, labels, or lot codes); 2) the product has a short shelf life and is usually no longer available in the marketplace when it is implicated in an outbreak; and 3) the contamination of fresh produce is usually sporadic and does not pose an ongoing risk to consumers. When a fresh produce product is implicated in an outbreak and there is a real or potential risk to the public's health, an entire industry is usually adversely affected as a result.

Confidentiality Agreements

All federal agencies are charged with protecting public health. It is imperative that information be shared between agencies working on the same investigations. The FDA is currently developing formats for agreements with other federal and state agencies that will allow the sharing and protection of commercial confidential information, including traceback information.

FDA and CDC, as sister agencies under the U.S. Department of Health and Human Services, have signed an agreement that assures the confidentiality of regulatory and health data that are shared between the agencies. Many states have also signed agreements with FDA that will allow this information to be shared and protected. In addition, many state food regulatory agencies have individuals who are "commissioned" by the FDA. In essence, these persons are issued FDA credentials and are able to receive information as FDA investigators. They can request and receive certain investigatory information, including traceback information, but cannot share the

information with others in their agency unless they are also “FDA Commissioned Officers” and have been approved by FDA to receive that information. These FDA Commissioned Officers can lose their credentials for releasing confidential information.

The role of industry in traceback investigations

Local and state agencies and trade groups are encouraged to work with industries in their area to facilitate the traceback of implicated products through improved product distribution record keeping throughout the distribution system. Industry should take an active role in developing and implementing systems to trace products from farm to table. A quick and accurate traceback system that can identify implicated shipments can minimize impact to the industry by potentially reducing the amount of product that may need to be recalled and by ruling out other shipments of product that might otherwise be implicated.

Investigation of firms

For multistate outbreaks or any outbreak linked to product that was shipped in interstate commerce, federal regulatory agencies have jurisdiction over the products and the responsible firms (e.g., processing, packing, or distributing companies). It is the responsibility of the federal regulatory agency to conduct an investigation at the firm(s). State regulatory investigators in the state where the firm is located are usually included in these outbreak response investigations.

Investigators in regulatory agencies are trained and required to list observations and not to make conclusions during an inspection or investigation. Investigations that are conducted in response to a foodborne outbreak require additional preparation by the investigators so that their observations are relevant to the situation. Federal and state regulatory agencies are encouraged to consult with experts in epidemiology, traceback, and microbiology, particularly those who have knowledge about the outbreak investigation, as well as experts in food and water processing, manufacturing, and farming.

State and federal regulatory agencies should have an understanding of the outbreak, (e.g., distribution of the illnesses, dates of exposure, microbiology of the pathogen). These agencies should discuss and review the epidemiologic findings before conducting an investigation at the firm. In some instances, it may be appropriate to involve experts in specific areas (e.g., microbiologists, water or plant engineers, epidemiologists) to assist in the investigation as they may have a particular perspective that otherwise would not be available.

Appendix A. Federal Emergency Contacts

Agency	Contact Office	Phone Number(s)	Fax Numbers
HHS			
Centers for Disease Control and Prevention, Atlanta, GA	Main Emergency Number (24 hour operator)	404-639-3311	
	Foodborne and Diarrheal Diseases (bacterial and unidentified pathogens)	404-639-2206	404-639-2205
	Parasitic Diseases	770-488-7750	770-488-7761
	Viral Diseases/ Hepatitis	404-371-5900	404-371-5221
	Viral Diseases/ Gastroenteritis Branch (Norwalk-like viruses)	404-639-6307	404-639-3866
	Vessel Sanitation Program	770-488-7070 800-323-2132	770-488-4127
	Division of Quarantine	404-639-8110	
Food and Drug Administration Rockville, MD	Emergency Operations (emops1@ora.fda.gov)	301-443-1240 (24 hours)	301-443-3757
USDA			
Food Safety and Inspection Service Washington, DC	Emergency Response Branch	202-690-6413 After Hours pager 800-759-8888 PIN 4124058	202-690-6414
EPA			
Environmental Protection Agency Washington, DC	Office of Research & Development	513-569-7689	
	Office of Ground Water and Drinking Water	202-260-7096	
	Office of Pesticide Programs	703-305-7576	703-305-4646

Appendix B. FSIS (USDA) District Offices

District	Phone Number	Fax Number	Area of Responsibility
Alameda	510-337-5000	510-337-5081	CA
Salem	503-399-5831	503-399-5636	AK, AS, GM, NMI, HI, ID, OR, WA
Boulder	303-497-5411	303-497-7306	AZ, CO, NM, NV, UT
Minneapolis	612-370-2400	612-370-2411	MN, MT, ND, SD, WY
Des Moines	515-727-8960	515-727-8991	IA, NE
Lawrence	785-841-5600	785-841-5623	KS, MO
Springdale	501-751-8412	501-751-9049	AR, LA, OK
Dallas	214-767-9116	214-767-8230	TX
Madison	608-240-4080	608-240-4092	MI, WI
Chicago	630-620-7474	630-620-7599	IL, IN
Pickerington	614-833-1405	614-833-1067	KY, OH, WV
Philadelphia	215-597-4219	215-597-4217	PA
Albany	518-452-6870	518-452-3118	CT, ME, MA, NH, NJ, NY, RI, VT
Beltsville	301-504-2136	301-504-2140	DE, DC, MD, VA
Raleigh	919-844-8400	919-844-8411	NC, SC
Atlanta	404-562-5900	404-562-5877	FL, GA, PR
Jackson	601-965-4312	601-965-4993	AL, MS, TN

Appendix C. FDA District Offices

District	Phone Number	Fax Number	Area of Responsibility
Atlanta	404-253-1169	404-253-1205	GA, SC, NC
Baltimore	410-962-3396	410-962-2219	MD, VA, DC, WV
Chicago	630-978-5763	312-886-3280	IL
Cincinnati	513-679-2700	513-679-2771	OH, KY
Dallas	214-655-5310	214-655-5331	TX, OK, AR
Denver	303-231-6466	303-236-3551	CO, UT, WY, NM
Detroit	313-927-8268	313-226-3076	MI, IN
Florida	407-475-4700	407-475-4768	FL
Kansas City	913-599-9635	913-752-2413	KS, NE, IA, MO
Los Angeles	714-667-7216	949-798-7690	So. CA, AZ
Minneapolis	612-392-4314	612-334-4134	MN, ND, SD, WI
New Orleans	504-240-4500	504-253-4566	LA, MS
Nashville	615-781-5385	615-781-5383	TN, AL
New England	781-939-2380	781-279-1742	VT, NH, ME, MA, CT, RI
New Jersey	973-905-4205	973-526-6069	NJ
New York	718-340-7000	718-662-5660	NY
Philadelphia	215-597-4390	215-597-0875	PA, DE
San Francisco	510-337-6700	510-337-6859	No. CA, NV, HI
Seattle	425-486-8788	425-483-4996	WA, OR, ID, MT, AK
San Juan	787-729-6943	787-729-6809	PR, VI

Appendix D. TEMPLATE FOR LOCAL AND STATE CONTACTS

Agency	Contact Name/Office	Phone Number	Fax Number	Email

Appendix E.

Foodborne/Waterborne Outbreak Early Alert Fax/Email Template

To: **Fax:**

From: **Phone:**

CC: **Date:**

This is an early alert/heads up on an investigation we are conducting. The information contained in this fax should be considered preliminary and confidential. This information should not be shared or distributed without permission from the sender. If you have similar cases, please notify the appropriate agency or agencies in your jurisdiction.

The _____ Health Department is currently investigating an outbreak that is suspected to be

foodborne _____
waterborne_____
of unknown source/vehicle _____

Number of cases _____ **Number of clusters_____**

Earliest onset date_____ **Latest onset date_____**

Pathogen/Agent _____ (suspected/confirmed)

Food/Water Product _____ (suspected/implicated/lab confirmed)

Place(s) of Exposure _____

Details:

Our agency's lead contact is:

Name:
Phone Number:
Fax Number:

Confidential

Appendix F. Checklist for Communicating Findings

Epidemiologic Investigation:

__ Definition of illness (or case definition if case-control study)

__ Number of ill persons (or number of cases if case-control study)

__ Number hospitalized and any fatalities

__ Number exposed

__ Dates, times of onset of illness and exposures

__ List of symptoms, duration and frequency

__ Location(s) of illness occurrence

__ A copy of the questionnaire

__ Description of study design

__ Criteria used to select or exclude study participants

__ Number of persons enrolled in study

__ If matching is used, criteria for matching

__ List of foods and other variables assessed

__ Portion size of food consumed (if available)

Analysis and Results

__ Plot of the epi curve

__ Food-specific attack rate (if cohort study)

__ 2 x 2 contingency table(s)

__ Pertinent measures of association and statistics

__ How potential confounding factors were controlled

__Dose-response effect (if data available)

Environmental Investigation:

__ Identification of suspected agent and vehicle

- If a pesticide is suspected, collect the exact product name and EPA registration number and active ingredients (if known).

__ Review of food worker illnesses and absences

__ Collection of food worker specimens (if appropriate. See food worker under "Laboratory samples")

__ Food preparation review of implicated foods, including times and temperatures

__ Assessment of water supply, potential cross connections

__ Assessment of sewage disposal system and any opportunities for wastewater backup into food, sinks, or equipment

__ Assessment of traps and drains as a potential source of contamination

__Results of surface swabs, if collected

__ Labels and descriptive information on products, where available

__ Records of sale/shipment for one shelf life of product (harvest-to-table shelf life)

__ Results of samples of the implicated food, where available and appropriate

__ Results of environmental swabs (surface and utensil swabs)

__ Results of sample controls

__ Food worker/food safety training/knowledge

__ List possible contributing factors

Laboratory Investigation

Clinical Specimen and Food Sample Collection:

__ Clinical samples for suspected agent from symptomatic and asymptomatic exposed individuals

- Stools
- Vomitus
- Serum
- Urine
- Other, specify_____

__ Specimen(s) from food workers
- Stools
- Swabs from hands, nose and throat

__ Food samples
- Home samples
- Restaurant or point of sale/service (POS) samples
- Unopened container/packages of the same lot as suspected product(s)
- Samples from production facility

__ Environmental samples
- Swabs from POS,
- Swabs from production/distribution facility
- Water samples from POS
- Water samples from production facility

Standard Criteria:

__ Additional samples and isolates

__ Analytical methods used

__ Enumeration and/or quantification of results

__ Laboratory-confirmed cases match case definition

__ Secondary testing results (serotyping, PFGE, antibiotic sensitivity)

__ Sharing/confirming of secondary testing results from appropriate epi surveillance (PulseNet, federal, and/or state labs). Determine if there are a sufficient number of historical patterns to estimate variability

__ Name of laboratories analyzing specimen(s) and sample(s)

__ Results of laboratory analysis and controls

Appendix G. Conference Call Etiquette

Host

1. Make and distribute agenda at least 2 days before the conference call, when possible.
   The agenda should include
   Name and affiliation of the facilitator/convenor
   Format for reporting information

2. Distribute handouts in advance.

3. Identify host/leader of call.

4. Identify and notify point of contact in all relevant agencies.

5. Take attendance, make introductions.

6. Explain jargon, abbreviations.

7. Stay on topic, stay on time.

8. Solicit everyone's input.

9. Record and distribute a summary of the call including action items and plans for the next meeting, if known.

All Participants

1. Do not put the conference call on hold. Some phones will play background music when on hold, disrupting the call.

2. Do not use a cell phone, as this often disrupts the call and makes other participants unable to hear.

3. Identify yourself and affiliation when you log on to the call.

4. After identifying yourself, please put your phone on mute and leave it on mute until you wish to speak. After speaking return the phone to mute.

5. Explain jargon, abbreviations.

6. Stay on topic, stay on time.

7. Identify self and organization before speaking.

Appendix H. Roles and Responsibilities of Federal Agencies in Foodborne Outbreak Investigations

- **FSIS** The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) is responsible for assuring that meat, poultry, and pasteurized processed egg products are not adulterated or misbranded. FSIS has the regulatory authority to coordinate a voluntary recall of meat, poultry and pasteurized processed egg products linked to outbreaks of foodborne disease. During foodborne illness outbreaks, FSIS is available to assist local, state and other federal agencies in their investigations. FSIS epidemiology officers can assist in tracing the origin and distribution of meat, poultry and egg products and can provide laboratory assistance to identify the contaminant(s) in the implicated product. FSIS has experience in working with state health and agriculture departments and knowledge of production practices of meat, poultry, and pasteurized processed egg products. FSIS can provide coordination, laboratory support, technical consultation, regulatory support, and media relations.

  FSIS's main objective is to remove quickly from commerce product that is known to be contaminated with harmful agents. If illnesses are associated with meat, poultry, or egg products, health department officials should contact the local FSIS Offices (Appendix B). The district offices will contact Human Health Sciences Division, Emergency Response Branch (7:30 a.m. to 4:30 p.m.) at 202-690-6413. For after- hours emergencies contact the epidemiologist on call by beeper 1-800-759-8888 (pin #4124058).

- **FDA** The Food and Drug Administration (FDA) regulates the safety of all foods, including shell eggs, that move in interstate commerce, except for meat, poultry, and pasteurized processed egg products regulated by FSIS. FDA's objectives in outbreak investigation and response are verification of the association of illness with a regulated product, identification of the source of the product and its extent of distribution, prevention of any further exposure to the contaminated product, and initiation of regulatory action as indicated. In addition, to determine contributing factors so similar problems can be avoided in the future, FDA has the regulatory authority to coordinate a voluntary recall of FDA-regulated products that are linked to outbreaks of foodborne disease. FDA works with other federal agencies as well as state and local agencies to assure efficient and expeditious investigation and response. FDA can provide coordination, field investigators, laboratory support and surveillance, technical consultation, regulatory support, and media relations. Additionally, FDA provides policy, technical, and scientific support to these investigations. FDA scientists, consumer safety officers, and laboratory personnel provide technical and scientific advice/support to field investigators during an outbreak investigation.

  Twenty District Offices located in five Regions carry out FDA's investigation and outbreak response activities. The FDA District Offices are the primary points of contact for state and local government agencies and the food industry (Appendix C). The District Offices are equipped with a 24-hour answering service. FDA's outbreak response is coordinated by the Division of Emergency and Investigational Operations (DEIO). DEIO can be contacted 24 hours a day, seven days a week at 301-443-1240.

- **CDC** The Centers for Disease Control and Prevention (CDC) works closely with state and local public health epidemiologists and laboratorians to identify illnesses and clusters of illness that may be foodborne, to conduct the rapid epidemiologic investigations needed to implicate foods or other sources of infection, to determine risk factors for illness, and to develop prevention and control strategies. CDC does this by epidemiologic consultation with the state and local epidemiology offices, on-site emergency assistance in epidemiologic investigations, provision of reference diagnostic support to the state public health laboratory, and development and application of subtyping protocols for foodborne pathogens. CDC is not a regulatory agency but works with regulatory agencies during outbreak investigations to determine the origins of contaminated food and the reasons for the contamination. Epidemiologists and microbiologists in state public health departments have phone, FAX, and e-mail addresses for their routine CDC contacts. In an emergency, CDC may be contacted 24 hours a day at 404-639-3311.

- **EPA** The U.S. Environmental Protection Agency (EPA) maintains the capability to respond to waterborne disease outbreaks. Generally these outbreaks are identified by either a state or county health department, who in turn contacts the state environmental agency and CDC. If CDC agrees that the disease may be associated with drinking water, it or the state or both will contact EPA to request assistance in identifying the causes of the outbreak.

  EPA has established a coordination system for responding to outbreaks. The National Risk Management Research Laboratory (NRMRL) in the EPA's Office of Research and Development (ORD) should be contacted at 513-569-7689. The NRMRL is responsible for providing staff in response to outbreaks and, through the Water Supply and Water Resources Division (WSWRD), provides a field response team and laboratory analytical capabilities, either directly or through support contract. Additionally, contact should be made with the EPA's Office of Ground Water and Drinking Water (202-260-5543/7096) to allow a coordinated outbreak response.

  In addition, WSWRD and other elements of ORD will respond to requests from Regional Offices, municipalities and state agencies if water quality problems are associated with individual water utilities. Frequently these problems are associated with violations of the Maximum Contaminant Levels under the Safe Drinking Water Act but have not been categorized as waterborne outbreaks.

  EPA's Office of Prevention, Pesticides & Toxic Substances administers the Toxic substances Control Act, the Pollution Prevention Act, and the Federal Insecticide, Fungicide & Rodenticide Act (FIFRA) and has a system of criminal and civil penalties to enforce these measures. Through cooperative enforcement agreements, all but two states have assumed primary enforcement responsibilities for pesticide violations under FIFRA, subject to EPA oversight. Through this system, EPA ensures that pesticides used on crops/food are registered, not adulterated, and used according to label directions. Investigations are done on pesticide incidents and incidents of chemical contamination. In cases of pesticide incidents or emergencies, the Office of Pesticide Programs (OPP) should be contacted at 703-305-7576.

Appendix I (a). Multistate Foodborne Disease Outbreak Matrix by Agency Level

Level	Surveillance	Detection	Investigation	Food Association	Traceback	Source Investigation
Local	• Reportable disease • Sporadic cases	• Cluster identification • Complaint follow-up	• Assemble team • Active case finding • Patient interviews • Verify diagnosis	• Descriptive epi • Statistical association • Environmental investigation • Match lab isolates • Alert other agencies	• Collect source information • Share findings with state/ federal	• Support state/ federal investigation
State	• Consult with local staff • Receive reports from local staff • Identify trends	• Consult with local staff • Receive reports from local staff	• Assist local staff • Expand investigation • Coordinate investigation	• Alert other agencies • Assist local staff • Statewide coordination • Alert public	• Collect source information • Share findings with federal	• Support federal source investigation • Conduct source investigation • Identify contributing factors
Federal	• Consult state/local staff • Public health labs • FDA/USDA labs • SODA, FoodNet, PulseNet, Food Pesticide Labs	• Consult state/local • Conduct additional lab tests • Epi aid	• Coordinate investigation • Epi aid • Lab testing • Alert other agencies	• Coordinate investigation • Verify food association • Expand investigation • Alert public/ recall	• Collect source info at all levels of distribution • Analyze trace information • Identify source	• Lead source investigation • Identify violations & contributing factors • Implement enforcement/ interventions

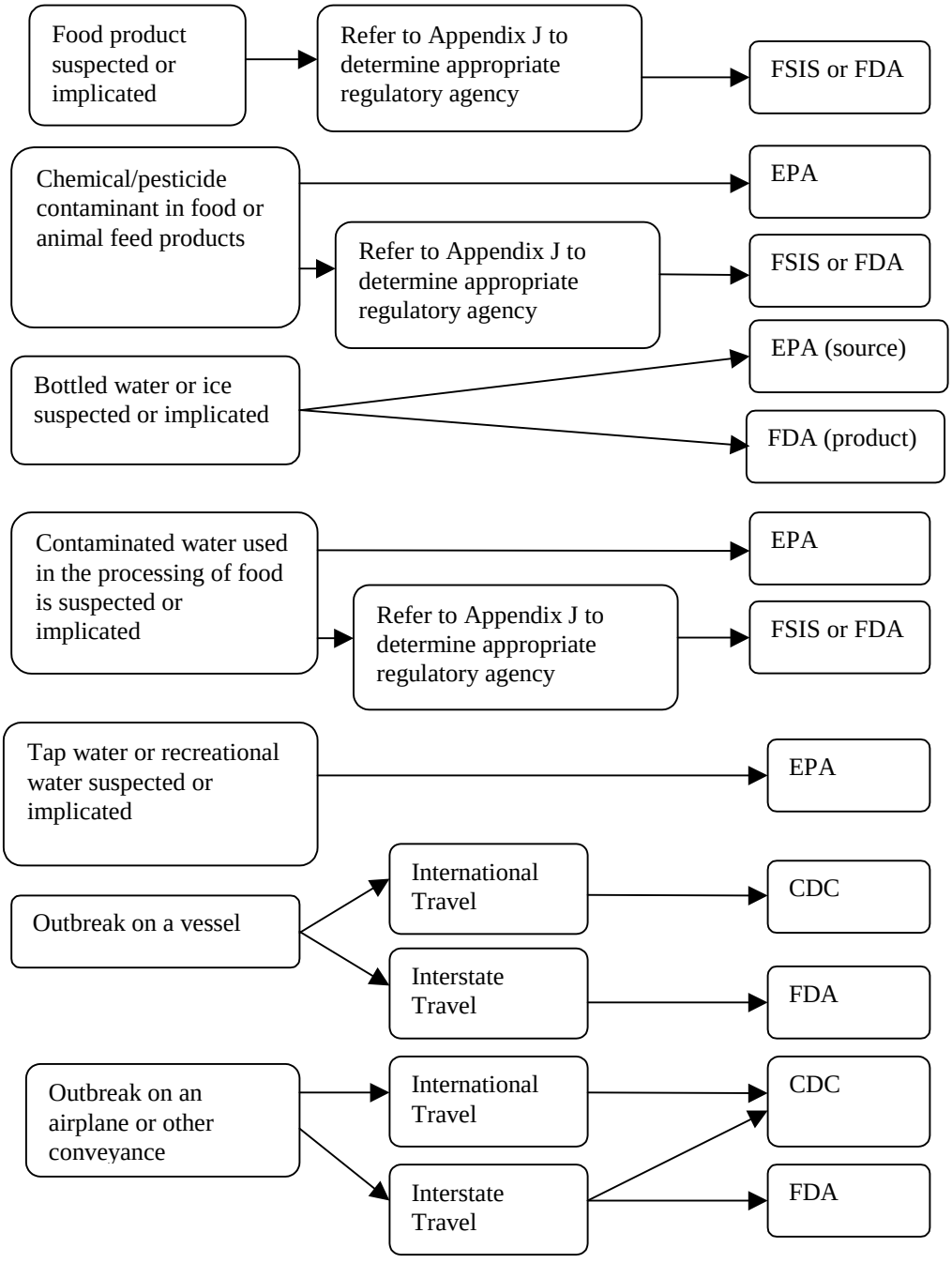
Appendix I (b). Multistate Foodborne Disease Outbreak Matrix by Function

Function	Surveillance	Detection	Investigation	Food Association	Traceback	Source Investigation
Epidemiology	• Passive (reportable-SODA) • Active (FoodNet) • Complaint response	• Cluster identification • Complaint follow-up • Verify diagnosis	• Expand investigation • Case finding • Assemble team • Coordinate investigation	• Descriptive epi • Statistical association • Verify food association • Alert public/recall	• Determine source(s)	• Support environmental investigation of source
Laboratory	• Clinical labs • PulseNet • Public Health labs • Food pesticide labs • FDA/USDA labs	• Match patient isolates • Secondary tests • Review of previous isolates (PFGE patterns) • Food samples	• Match patient isolates • Secondary tests	• Analyze food/ environmental samples • Match patient and food isolates	• Share findings and support investigation	• Analyze food/ environmental samples
Environmental	• Complaint response investigation • Inspection data	• Alert epidemiology • Complaint follow-up	• Expand investigation • Investigate place of preparation	• Investigate place of preparation • Verify food/water association • Determine if contamination occurred at point of preparation • Alert public/recall	• Collect source information throughout distribution • Collect and analyze traceback information • Determine source	• Lead source investigation • Identify contributing factors/violations • Collect samples • Implement enforcement/interventions

Appendix J. FDA/USDA Jurisdictional Overlap for Commercial Food Products

PRODUCT	FDA	USDA
Red meat products	Nonspecified red meats, e.g., bison, rabbit, game animals, zoo animals, elk, wapiti, moose	Cattle, sheep, swine, goats, horses, mules, other equine
Poultry	Nonspecified birds: wild turkeys, wild ducks, wild geese, emus, ratites	Domesticated birds: chicken, turkey, ducks, geese, guineas
Other meat products	Products containing <3% red meat (wet) and closed faced meat sandwiches	Products containing 3% or more red meat (wet) and open-faced meat sandwiches
Other poultry products	Products containing < 2% poultry (wet)	Products containing 2% or more poultry (wet)
Eggs	Shell eggs, products containing egg products and other egg processing not covered by USDA (e.g., restaurants, cake mix plants, bakeries). Enforcement of shell egg labels/ labeling	Pasteurized processed egg products, egg processing plants (washing, sorting, breaking, and pasteurizing)
Soup	All soup not covered by USDA	Soup containing 3% or more red meat or 2% or more poultry (e.g., chicken noodle)
Other products	Cheese, onion, mushroom, pizza, spaghetti sauces (less than 3% red meat), spaghetti sauce with mushrooms and 2% meat, pork and beans, sliced egg sandwich (closed faced), frozen fish dinner, rabbit stew, shrimp flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets	Pepperoni pizza, meat lovers stuffed crust pizza, meat sauces (3% or more red meat), spaghetti sauce with meatballs, open faced roast beef sandwich, hot dogs, beef/veg pot pie, chicken sandwich (open faced)
Exceptions to the above	All foods involved in an outbreak aboard an interstate vessel, plane, train, bus	

Appendix K. Determining Federal Regulatory Jurisdiction



Appendix L. Suggested Table of Contents for a Basic Operating Procedure Manual for Multistate Foodborne Outbreaks

A. Contact Lists
   1. Local and state agencies (Health, Environmental, Agriculture)
   2. FSIS and FDA District Offices
   3. Federal agencies (CDC/HHS, FSIS/USDA, FDA/HHS, EPA)

B. Roles and Responsibilities of Food Safety Agencies
   1. Federal agency jurisdictions
   2. Flow diagram for determining federal regulatory jurisdictions

C. Public health communication information/agent fact sheets
   1. Press kit (contacts, sample press releases)

D. Outbreak Investigation Procedures
   1. Outbreak investigation procedures
   2. Critical data points to collect
   3. Conference call etiquette
   4. Lab reference sheet (collection, shipping, storage, methods)
   5. Guidelines for multistate outbreak coordination

E. Outbreak Investigation Forms
   1. Early alert fax template
   2. Standardized questionnaires
   3. Food prep review/environmental investigation template
   4. CDC outbreak reporting form

F. Reference Materials/Bibliography

G. Glossary

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CDC Foodborne Outbreak Response and Surveillance Unit
http://www.cdc.gov/ncidod/dbmd/fddb/outbreak

CDC Form 52.13 Foodborne Outbreak Report Form (Rev 8/99)
http://www.cdc.gov/ncidod/dbmd/fddb/outbreak/report_f.htm

Epidemiologic Case Studies: http://www.cdc.gov/phtn/casestudies/dnload.htm

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Acronyms Commonly Used in Food Safety

AFDO – Association of Food and Drug Officials

ANSI – American National Standards Institute

APHL – Association of Public Health Laboratories (formerly ASTPHLD – Association of State and Territorial Public Health Laboratories)

CDC – Centers for Disease Control and Prevention

CFSAN – Center for Food Safety and Applied Nutrition (FDA)

CSTE – Council of State and Territorial Epidemiologists

DEIO – Division of Emergency and Investigational Operations (FDA)

EIR – Establishment Inspection Report

EPA – Environmental Protection Agency

FDA – U.S. Food and Drug Administration

FIFRA – Federal Insecticide, Fungicide, and Rodenticide Act

FOIA – Freedom of Information Act

FORCG – Foodborne Outbreak Response Coordination Group

FQPA – Food Quality Protection Act

FSIS (USDA) – Food Safety Inspection Service (U.S. Department of Agriculture)

HACCP – Hazard Analysis Critical Control Points

IAFP (formerly IAMFES) – International Association for Food Protection formerly International Association of Milk, Food and Environmental Sanitarians

IAMFES (now IAFP)- International Association of Milk, Food and Environmental Sanitarians (now International Association for Food Protection)

IOM – Investigational Operations Manual (FDA)
IOM – Institute of Medicine

ISO – International Standards Organization

NACCHO – National Association of County and City Health Officials

NAIN – National Antimicrobial Information Network (EPA)

NCID – National Center for Infectious Diseases (CDC)

NEDSS – National Electronic Disease Surveillance System (formerly NETSS National Electronic Telecommunications Surveillance System

NFSS – National Food Safety System

NPTN – National Pesticide Telecommunications Network (EPA)

NSSP – National Shellfish Sanitation Program

OPP – Office of Pesticide Programs (EPA)

OPPTS – Office of Prevention, Pesticides and Toxic Substances (EPA)

ORA – Office of Regulatory Affairs (FDA)

ORD – Office of Research and Development (EPA)

ORO – Office of Regional Operations (FDA)

OW – Office of Water (EPA)

PFGE – Pulsed-Field Gel Electrophoresis

PHLIS – Public Health Laboratory Information System

SODA – Salmonella Outbreak Detection Algorithm

TSCA – Toxic Substances Control Act

WHO – World Health Organization

Glossary

2 x 2 table - a tabular cross-classification of data such that subcategories of one characteristic are indicated horizontally (in rows) and subcategories of another characteristic are indicated vertically (in columns). Tests of association between characteristics in the columns and rows can be readily applied. Also known as a contingency table. The simplest contingency table is the fourfold or 2 x 2 table. Contingency tables may be extended to include several dimensions of classification.

	ill	not ill
Exposed	a	b
Not Exposed	c	d

Agent - a factor, such as a microorganism, chemical substance, or form of radiation, whose presence, excessive presence, or (in deficiency diseases) relative absence is essential for the occurrence of a disease. A disease may have a single agent, a number of independent alternative agents (at least one of which must be present), or a complex of two or more factors whose combined presence is essential for the development of the disease.

Antibiogram - a record of the resistance of microbes to various antibiotics.

Asymptomatic - without symptoms or producing no symptoms.

Attack rate - the cumulative incidence of infection in a group observed over a period during an epidemic; the proportion of ill among those exposed. This "rate" can be determined empirically by identifying clinical cases and/or by means of seroepidemiology. Because its time dimension is uncertain or arbitrarily decided, it should probably not be described as a rate.

Carrier - A person or animal that harbors a specific infectious agent in the absence of discernible clinical disease and serves as a potential source of infection. The carrier state may occur in an individual with an infection that is inapparent throughout its course (known as healthy or asymptomatic carrier) or during the incubation period, convalescence, and postconvalescence of an individual with a clinically recognizable disease (known as incubatory carrier or convalescent carrier). The carrier state may be of short or long duration (temporary or transient carrier or chronic carrier).

Case - A particular instance of a disease, health disorder, or condition under investigation. A variety of criteria may be used to identify cases, e.g., individual physicians' diagnoses, registries and notifications, abstracts of clinical records, surveys of the general population, population screening, and reporting of defects such as in a dental record. The epidemiologic definition of a case is not necessarily the same as the ordinary clinical definition.

Case-control study - the observational epidemiologic study of a person or persons with the disease (or other outcome variable) of interest and a suitable control (comparison, reference) group of persons without the disease. The relationship of an attribute to the disease is examined

by comparing the diseased and nondiseased with regard to how frequently the attribute is present or, if quantitative, the levels of the attribute, in each of the groups. In short, the history of exposure to suspected risk factor is compared between "case patients" and "controls," persons who resemble the case patients in such respects as age and sex but do not have the disease or condition of interest.

Case definition – the characteristics (typically time, place, person, and clinical features or symptoms) of the case being studied. This definition might be different in different phases of an investigation. For example, a broad definition might be used early in the course of an investigation to capture all possible cases; later in the investigation, the definition might be narrowed to capture only definite cases. Often, a "possible" and a "confirmed" case definition are generated, with the latter being, for example, a positive laboratory test result in addition to symptoms.

Case finding - the process of identifying all possible cases; this typically uses a broad case definition (see above) and occurs early in the investigation. Later in the investigation, case finding might be performed to assess the extent of the outbreak.

Chain of custody - a record which establishes the complete chronological disposition of an entity of concern, e.g. a sample or a document.

Cluster - aggregation of relatively uncommon events or diseases in space and/or time in amounts that are believed or perceived to be greater than could be expected by chance. Putative disease clusters are often perceived to exist on the basis of anecdotal evidence, and much effort may be expended by epidemiologists and biostatisticians in demonstrating whether a true cluster exists. With modern molecular laboratory techniques, clusters of infections with "identical" organisms are being uncovered; the significance of these clusters is currently a topic of discussion.

Cohort study - the analytic method of epidemiologic study in which subsets of a defined population can be identified who are, have been, or in the future may be exposed or not exposed, or exposed in different degrees, to a factor or factors hypothesized to influence the probability of occurrence of a given disease or other outcome. The main feature of cohort study is observation of large numbers over a long period (commonly years) with comparison of incidence rates in groups that differ in exposure levels. The alternative terms for a cohort study, i.e., follow-up, longitudinal and prospective study, describe an essential feature of the method, which is observation of the population for a sufficient number of person-years to generate reliable incidence of mortality rates in the population subsets. This generally implies study of a large population, study of a prolonged period (years), or both. However, traditional outbreak investigations often begin with a cohort study, with the study population being those in attendance at a particular meal or who had eaten at a restaurant during a particular time and exposure being defined as eating a particular item or meal.

Commercial confidential – trade secrets that are protected by law from public disclosure (e.g., monitoring records, customer lists, and traceback information). Unlawful release of this information can result in legal punishment including imprisonment.

Common source outbreak - outbreak due to exposure of a group of persons to a noxious influence that is common to the individuals in the group. When the exposure is brief and essentially simultaneous, the resultant cases all develop within one incubation period of the disease (a "point" or "point source" outbreak).

Confidence intervals (CI) - the computed interval with a given probability, e.g., 95%, that the true value of a variable such as a mean, proportion, or rate is contained within the interval. This is a measure of statistical significance; if a confidence interval includes the value 1.0, the study findings are said to be not statistically significant at the given level of certainty.

Confirmation - diagnosis of most diseases can be confirmed only if etiologic agents are isolated and identified from specimens obtained from ill persons.

Confirmed cases - usually cases that have met the case definition (see above) for symptoms AND in which infection is verified by laboratory test (e.g., culture)

Confirmed outbreak - clusters (see above) which are confirmed by laboratory or epidemiologic study to be caused by a common agent or to have occurred among persons who have shared a common exposure.

Confounding -

1. A situation in which the effects of two processes are not separated. The distortion of the apparent effect of an exposure risk brought about by the association with other factors that can influence the outcome.
2. A relationship between the effects of two or more causal factors as observed in a set of data such that it is not logically possible to separate the contribution that any single causal factor has made to an effect.
3. A situation in which a measure of the effect of an exposure on risk is distorted because of the association of exposure with other factor(s) that influence the outcome under study.

Contaminant - an infectious agent or a chemical or physical hazard.

Contamination - the presence of an infectious, chemical, or physical agent or substances in or on water, milk, and food that has the potential to cause harm, including illness or injury.

Contamination factors –

1. Natural toxin
2. Poisonous substance intentionally added.
3. Poisonous or physical substance accidentally or incidentally added.
4. Addition of excessive quantities of ingredients that under these situations are toxic.
5. Toxic container or pipelines.

6. Raw product or ingredient contaminated by pathogens from animal or environment.
7. Ingestion of contaminated raw products.
8. Obtaining foods from polluted sources.
9. Cross-contamination from raw ingredient of animal origin.
10. Bare-hand contact by food worker.
11. Handling by an intestinal carrier of enteric pathogens.
12. Inadequate cleaning of processing or preparation equipment or utensils.
13. Storage in contaminated environment.

Contributing factors - factors that contribute to contamination and survival of the etiologic agents and perhaps also to their growth or amplification. These include

1. Factors that introduce or otherwise permit contamination
2. Factors that allow survival of or fail to inactivate the contaminant
3. Factors that allow proliferation of the etiologic agents.

Controls - subjects with whom comparison is made in a case-control study, randomized controlled trial, or other type of epidemiologic study. Selection of appropriate controls is crucial to the validity of epidemiologic studies and has been much discussed.

Culture confirmed - see confirmation.

Diarrhea (specific characteristics, number within a period of time) - an abnormally frequent discharge of semisolid or fluid fecal matter from the bowel. In foodborne disease outbreaks, diarrhea is most commonly defined as 3 or more loose, watery stools in a 24-hour period. Diarrhea can also be further described by such things as the presence of blood, greasy texture, or dark color.

Epi curve - a graphic plotting of the distribution of cases by time of onset. Epi curves help characterize an outbreak and give clues about the source of the outbreak (e.g., common or point source, secondary spread)

Epi traceback – a preliminary investigation of product distribution. It is used by epidemiologists to help distinguish between two or more implicated products, to strengthen an association, or to develop hypotheses.

Etiologic agent - see agent

Exposure -

1. Proximity and/or contact with a source of a disease agent in such a manner that effective transmission of the agent or harmful effects of the agent may occur.
2. The amount of a factor to which a group or individual was exposed, sometimes contrasted with dose, the amount that enters or interacts with the organism.

Note: Exposures may be beneficial as well as harmful; e.g., exposure to immunizing

agents.

Firm - any individual, partnership, corporation, or association that deals in articles subject to the FD&C Act.

Food preparation review - a review done on each food or menu item that has been implicated in an outbreak. The review focuses on possible means of contamination, growth, or survival of pathogens. Food preparation reviews include a detailed step-by-step observation of the processes used in making, serving, storing, and transporting the implicated food item. Measurements such as times, temperatures, pH, size of containers/cooking vessels/cooling/storage containers, and amounts of ingredients/products must be included in a food preparation review. An example is given in the Procedures to Investigate Foodborne Illness, 5th edition, IAMFES.

Food-specific attack rate - a comparison of the illness rate among those who ingested specific foods at an event or meal with the illness rate of those who were at the event or meal but did not ingest these items. A food-specific attack rate table is used for cohort studies when the entire group at the event is known and interviewed about illness and exposure.

Food worker - person directly involved in producing, harvesting, processing, packaging, preparing, or storing the food under investigation.

FoodNet – Foodborne Disease Active Surveillance Network; a surveillance network coordinated by CDC, FDA, and FSIS/USDA among several state health departments, designed to provide more accurate estimates of the number and source of cases of foodborne illness in the United States.

HACCP (Hazard Analysis and Critical Control Point) - a prevention-based food safety system that identifies and monitors specific foodborne hazards--biological, chemical, or physical properties--that can adversely affect the safety of the food product. This hazard analysis serves as the basis for establishing critical control points (CCPs), those points in the process that must be controlled to assure the safety of the food. Further, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system, again, to assure that potential risks are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a HACCP plan.

Host -

1. A person or other living animal, including birds and arthropods, that affords subsistence or lodgment of an infectious agent under natural conditions. Some protozoa and helminthes pass successive stages in alternate hosts of different species. Hosts in which the parasite attains maturity or passes its sexual state are primary or definitive hosts; those in which the parasite is in a larval or asexual state are secondary or intermediate hosts. A transport host is a carrier in which the organism remains alive but does not undergo development.

2. In an epidemiologic context, the host may be the population or group; biological, social, and behavioral characteristics of this group that are relevant to health are called "host factors."

Hypothesis -

1. A supposition arrived at from observation or reflection that leads to refutable predictions.
2. Any conjecture cast in a form that will allow it to be tested and refuted.
3. Initial interviews with ill persons in an outbreak are often done to generate hypotheses about the cause of the outbreak and are typically more open-ended than interviews of case-patients and controls.

Implicated food - Food thought to be the outbreak vehicle, i.e., food thought to have made people ill, based on laboratory results and/or epidemiologic evidence.

Incubation period - The time interval between invasion by an infectious agent and appearance of the first sign or symptom of the disease in question.

Infection - the entry and development of multiplication of an infectious agent in the body of humans or animals. Infection is not synonymous with infectious disease: the result may be inapparent or manifest. The presence of living infectious agents (e.g., pediculosis, scabies) on exterior surfaces of the body is called infestation. The presence of living infectious agents upon articles of apparel or soiled articles is not infection, but represents contamination of such articles.

Intentional contamination - a deliberate adding of a contaminant to food in quantities sufficient to cause illness. Contaminants added because of sabotage, mischievous acts, and intents to cause panic or blackmail a company fall into this category.

Investigator -

Epidemiology: Any person involved in determining the agent, mode of transmission and factors leading to an illness or outbreak.

Regulatory: A person specially trained to collect evidence of violations of regulatory requirements. This evidence is collected for use in possible enforcement actions by the regulatory agency.

Market withdrawal - a firm's removal or correction of a distributed product that involves a minor violation for which FDA would not initiate legal action, or which involves no violation (e.g., normal stock rotation practices).

Matching - the process of making a study group and a comparison group comparable with respect to extraneous factors. Individual matching relies on identifying individual subjects for comparison, each of whom resembles a study subject on the matched variables. Matching is performed to reduce confounding (see above). Studies using matching in the interview phase must use matching in the analysis phase.

Measure of association - a quantity that expresses the strength of association between variables. Commonly used measures of association are differences between means, proportions or rates, the rate ratio, the odds ratio, and correlation and regression coefficients.

Odds ratio (OR) – the ratio of two odds. The term odds is defined differently according to the situation under discussion. Using a standard 2 x 2 table, the odds ratio (cross-product ratio) is ad/bc.

	Case	Control
Exposed	a	b
Not exposed	c	d

Outbreak - an epidemic limited to localized increases in the incidence of a disease, e.g., in a village, town, or closed institution; upsurge is sometimes used as a euphemism for outbreak.

Pathogen - organism capable of causing disease (literally, causing a pathological process).

PCR - polymerase chain reaction – a form of molecular testing which allows the specific identification of an organism from small quantities of its DNA.

Pesticide - any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. Pests can be insects, mice and other animals, unwanted plants (weeds), fungi, or microorganisms like bacteria and viruses. Though often misunderstood to refer only to insecticides, the term pesticide also applies to herbicides, fungicides and various other substances used to control pests. Under United States law, a pesticide is also any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant. Common pesticides include algaecides, antifouling agents, antimicrobial agents, attractants, biocides, disinfectants and sanitizers, fungicides, fumigants, herbicides, insecticides, miticides, microbial pesticides, molluscicides, nematicides, ovicides, pheromones, repellents, rodenticides, defoliants, desiccants, insect growth regulators and plant growth regulators http://www.epa.gov/opp00001/whatis.htm .

PFGE – pulsed-field gel electrophoresis – a molecular method that allows for the specific classification of pathogens by "fingerprinting" the DNA from the pathogen; this method generates visually observable patterns which can be digitized and then compared with other pathogens of the same genus and species. Pathogens with patterns characterized as "indistinguishable" may have similar sources. Two persons or items yielding indistinguishable organisms are more likely to be related (i.e., be part of the same outbreak) than if the organisms with different PFGE patterns are isolated.

Point source outbreak – see common source outbreak

Proliferation/amplification factors – factors that allow proliferation of the etiologic agents:

1. Allowing foods to remain at room or warm-outdoor temperature for

several hours.
2. Slow cooling.
3. Inadequate cold-holding temperature.
4. Preparing foods a half-day or more before serving.
5. Prolonged cold storage for several weeks.
6. Prolonged time and/or insufficient temperature during hot holding.
7. Insufficient acidification
8. Insufficiently low water activity.
9. Inadequate thawing of frozen products.
10. Anaerobic packaging or modified atmosphere.
11. Inadequate fermentation.

Protocol – procedure

PulseNet – the National Molecular Subtyping Network for Foodborne Disease Surveillance; a network of laboratories throughout the United States that perform testing on foodborne pathogens using standard methods (currently PFGE) and compare results via images on a computer network.

p-value – a measure of the chance that the observed results would occur if the null hypothesis were true. The probability associated with a statistical hypothesis will help decide if there is a significant association between exposure and illness or if the results are due to chance (coincidence).

Questionnaire – a predetermined set of questions used to collect data on (e.g.) clinical characteristics, social status, or occupational group. This term is often applied to a self-completed survey instrument, as contrasted with an interview schedule.

Recall – A firm's voluntary removal or correction of a marketed product(s), including its labeling and/or promotional materials, that FDA or FSIS considers to be in violation of the laws it administers, and for which the agency would initiate legal action (e.g., seizure or the full range of administrative and civil actions available to the agency). "Recall" does not include a market withdrawal or stock recovery.

Regulatory authority – Agency that regulates (permits/licenses and inspects) the substance or establishment under consideration.

Relative Risk (RR) –-

1. The ratio of the risk of disease or death among those exposed to the risk among the unexposed; this usage is synonymous with risk ratio.
2. Alternatively, the ratio of the cumulative incidence rate in the exposed to the cumulative incidence rate in the unexposed, i.e., the cumulative incidence ratio.
3. The term relative risk has also been used synonymously with odds ratio and, in some

biostatistical articles, has been used for the ratio of forces of morbidity. The use of the term relative risk for several different quantities arises from the fact that for "rare" disease (e.g., most cancers) all the quantities approximate one another. For common occurrences (e.g., neonatal mortality in infants under 1500 g birth weight), the approximations do not hold.

Reservoir of infection –

1. Any person, animal, arthropod, plant, soil, or substance, or a combination of these, in which an infectious agent normally lives and multiplies, on which it depends primarily for survival, and where it reproduces itself in such a manner that it can be transmitted to a susceptible host.
2. The natural habitat of the infectious agent.

Sample size determination – the mathematical process of deciding, before a study begins, how many subjects should be studied. The factors to be taken into account include the incidence or prevalence of the condition being studied, the estimated or putative relationship among the variables in the study, the power that is desired, and the allowable magnitude of type I error.

Serotype (or serovar) – a subdivision of a species or subspecies distinguishable from other strains therein on the basis of antigenic character.

Source -

1. Source of contamination – the person, animal, object, or substance from which an infectious agent passes to a host. The source of infection such as an overflow of a septic tank contaminating a water supply or an infected cook contaminating a salad should be clearly distinguished from the source of contamination.

2. Source of product – the firm/farm where the product originated. The source of the product is determined through a product traceback investigation. It is not necessarily the source of the contamination or infection.

Sporadic case – occurring irregularly, haphazardly from time to time, and generally infrequently, e.g., cases of certain infectious diseases; also, a case NOT associated with a known outbreak.

Statistically significant association – statistical methods allow an estimate to be made of the probability of the observed or greater degree of association between independent and dependent variables under the null hypothesis. From this estimate, in a sample of given size, the statistical "significance" of a result can be stated. Usually the level of statistical significance is stated by the p-value.

Stop sale – a hold order that can be placed on implicated food that originates from an unapproved source, or that may be unsafe, adulterated, not honestly presented, not labeled according to law or otherwise not in compliance with food regulations. A stop sale prevents the

food from being sold to the public.

Strength of association – the magnitude of the measure of association (see above); for example, the size or value of the odds ratio is a measure of the strength of association between an exposure and an illness or other outcome—the larger the odds ratio, the stronger the association.

Study design – the procedures and methods, predetermined by an investigator, to be adhered to in conducting a research project.

Subtype – see serotype

Surveillance – the continuing scrutiny of all aspects of occurrence and spread of a disease that are pertinent to effective control. Included are the systematic collection and evaluation of 1) morbidity and mortality reports; 2) special reports of field investigations of epidemics and of individual cases; 3) isolation and identification of infectious agents by laboratories; 4) data concerning the availability, use, and untoward effects of vaccines and toxins, immune globulins, insecticides, and other substances in control; 5) information regarding immunity levels in segments of the population; and 6) other relevant epidemiologic data. A report summarizing these data should be prepared and distributed to all cooperating persons and others with a need to know the results of the surveillance activities. The procedure applies to all jurisdictional levels of public health from local to international. Serologic surveillance identifies patterns of current and past infection using serologic tests.

Active surveillance – agencies regularly contact reporting sources to elicit reports of illnesses. An active surveillance system is likely to provide more complete illness reporting but is more labor intensive and costly to operate.

Passive surveillance – agencies receive disease reports from physicians, the public, and institutions as mandated by state law.

Survival factors - factors that allow survival or fail to inactivate the contaminant:

1. Insufficient time and/or temperature during cooking or heat processing.
2. Insufficient time and/or temperature during reheating.
3. Inadequate acidification.
4. Insufficient thawing followed by insufficient cooking.

Suspected Case- an illness meeting part of the case definition (see above); for example, specific symptoms (and, perhaps, exposure to a food item of interest) but no laboratory test confirming the cause of the illness; can also refer to laboratory-confirmed illness in persons who are not known to have the exposure of interest.

Suspected Outbreak – a cluster of cases linked by time or space which have not been confirmed to be caused by the same agent or item (exposure) but which have characteristics (e.g., an unusual organism or exposure) which makes it likely that the cases are linked not by chance alone.

Suspected food - food from an implicated meal that is a likely vehicle for the causative agent. These foods are often identified in a food specific attack rate table.

Symptomatic - demonstrating clinical signs or symptoms; e.g., having diarrhea, abdominal pain, fever.

Time/temperature abuse - Insufficient time and/or temperature during cooking or heat processing; insufficient time and/or temperature during reheating.

Traceback (also referred to as a product or regulatory traceback) – the method used to determine the source and scope of the product/processes associated with an outbreak and document the distribution and production chain of the product that has been implicated in a foodborne illness or outbreak.

Traceforward - once the source of an implicated food item is established, investigators may do a "traceforward" to document the distribution of all implicated lots of food from the source. This can help epidemiologists with case finding and can be used to test hypotheses about the outbreak. Traceforwards should only be used when there is a reasonable degree of confidence that the traceback correctly identified the source of the implicated product. A product recall also involves a traceforward to determine the suppliers that received the product.

Vector - in infectious disease epidemiology, an insect or any living carrier that transports an infectious agent from an infected individual or its wastes to a susceptible individual or its food or immediate surrounding. The organism may or may not pass through a developmental cycle within the vector.

Vehicle (of infection transmission) - the mode of transmission of an infectious agent from its reservoir to a susceptible host. This can be (e.g.) person to person, food, or vector-borne.

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